S. Hrg. 98-1038

HEALTH CARE TECHNOLOGY ASSESSMENT

HEARING

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

NINETY-EIGHTH CONGRESS

SECOND SESSION

ON

EXAMINATION OF THE HEALTH CARE COST CONTAINMENT ISSUE: HEALTH TECHNOLOGY ASSESSMENT; GENERAL COST CONTAINMENT STRATEGIES; AND COST IMPLICATIONS OF DEFENSIVE MEDICINE AND MEDICAL MALPRACTICE

JUNE 7, 1984

Printed for the use of the Committee on Labor and Human Resources

U.S. GOVERNMENT PRINTING OFFICE
38-453 O WASHINGTON : 1984

55471

COMMITTEE ON LABOR AND HUMAN RESOURCES

ORRIN G. HATCH, Utah, *Chairman*

ROBERT T. STAFFORD, Vermont
DAN QUAYLE, Indiana
DON NICKLES, Oklahoma
JEREMIAH DENTON, Alabama
LOWELL P. WEICKER, Jr., Connecticut
CHARLES E. GRASSLEY, Iowa
JOHN P. EAST, North Carolina
PAULA HAWKINS, Florida
STROM THURMOND, South Carolina

EDWARD M. KENNEDY, Massachusetts
JENNINGS RANDOLPH, West Virginia
CLAIBORNE PELL, Rhode Island
THOMAS F. EAGLETON, Missouri
DONALD W. RIEGLE, Jr., Michigan
HOWARD M. METZENBAUM, Ohio
SPARK M. MATSUNAGA, Hawaii
CHRISTOPHER J. DODD, Connecticut

Ronald F. Docksai, *Staff Director*
Kathryn O'L. Higgins, *Minority Staff Director*

CONTENTS

STATEMENTS

THURSDAY, JUNE 7, 1984

Page

Brandt, Edward M., M.D., Assistant Secretary of Health, U.S. Department of Health and Human Services, accompanied by John Marshall, Director, National Center for Health Services Research 8
- Prepared statement 10

Dodd, Gerald D., M.D., prepared statement 125
Eddy, Dr. David M., director, center for health policy research and education, Duke University 119
Hatch, Hon. Orrin G., a U.S. Senator from the State of Utah, prepared statement 2
Kennedy, Hon. Edward M., a U.S. Senator from the State of Massachusetts, prepared statement 4
Knoebel, Suzanne B., M.D., chairman, government relations committee, American College of Cardiology 78
- Prepared statement 81

Leaf, Alexander, M.D., chairman, department of preventive medicine, Harvard Medical School, Boston, MA 41
- Prepared statement 43

Maynard, Dr., Edwin p., chairman, health and public policy committee, American College of Physicians 51
- Prepared statement 53

Morris, Lawrence C., senior vice president, Blue Cross & Blue Shield Association, Chicago, IL 28
- Prepared statement 31

Rolland, Ian, chief executive officer, Lincoln National Life Insurance Co., Fort Wayne, IN, representing the Health Insurance Association of America 39
Samuel, Frank E., president, Health Industry Manufacturers Association 90
- Prepared statement 93

Schwarz, M. Roy, M.D., vice president, medical education and science policy, American Medical Association 67
- Prepared statement 70

Thurmond, Hon. Strom, a U.S. Senator from the State of South Carolina, prepared statement 3
Young, Dr., Donald, executive director, Prospective Assessment Commission, Washington, DC 26

ADDITIONAL MATERIAL

Questions and answers:
- Responses of Mr. Morris to questions submitted by Senator Grassley 38
- Responses of Mr. Morris to questions submitted by Senator Kennedy 39
- Responses of Mr. Samuels to questions submitted by Senator Kennedy 115
- Responses of Mr. Samuels to questions submitted by Senator Grassley 119

HEALTH CARE TECHNOLOGY ASSESSMENT

THURSDAY, JUNE 7, 1984

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The committee met, pursuant to notice, at 9:45 a.m., in room 562, Dirksen Senate Office Building, Senator Dan Quayle (acting chairman of the committee) presiding.

Present: Senator Quayle.

OPENING STATEMENT OF SENATOR QUAYLE

Senator QUAYLE. The committee will come to order.

Today on behalf of Chairman Hatch I have the opportunity to hold hearings on health technology assessment. This will be the first in a series of three hearings that I have the opportunity to chair to examine the health care cost containment issue. The first will be today on health technology assessment. The second hearing will be on June 21. That will focus on general cost containment strategies—in other words, whether we should take a very comprehensive approach or should we have a more incremental approach. The hearing will basically be a dialog and the discussion that day and will determine how we will go forward. The third hearing will be held on July 10, and we will explore the cost implications of defensive medicine and medical malpractice.

After these hearings, obviously we will be in a better position to make a determination on where we are going to go in the whole health care area. In general, I have always been very up front in trying to approach this issue, as I do other issues, in a market-oriented fashion. I believe this approach is the best means to assure the desired ends of an efficient allocation and utilization of our health care resources.

I am concerned, however, that with respect to the application of new and existing health care technology, that perhaps the market alone may not provide sufficient information upon which to determine the best use of health care resources. It has become increasingly clear in recent years that there may also be insufficient incentives to promote the most cost effective use of new medical technologies.

By saying that, I don't mean that technology by itself is bad, because technology in and of itself is generally good. Technology by itself does not necessarily increase cost, but sometimes the utilization of technology is the issue on cost. I do believe that, as we are looking at and groping with technology—and I have always been one that has advocated entrepreneurship, incentives, and trying to go as far and as fast and as quickly as possible—we need to realize that cost is going to be a factor and that the cost factor in technology is here to stay.

I think what we are trying to examine today—and our leadoff witness can certainly give us some insight—is legislation that I have introduced and legislation that has been introduced in the House concerning how we can get knowledge about technology assessment and how we can disseminate that knowledge.

Furthermore, I think that the most important thing—and I hope all of our witnesses will direct themselves to it—is that we have talked a lot about public/private participation. How are we going to get the credibility that is necessary, so once a determination on technology assessment is reached, that it is going to be accepted, that it is going to be utilized, and how can we do this in the most efficient manner?

We have explored this in the past. We have done technology assessment and there are a lot of entities that do it but it has been pretty much a Government function. For political reasons the legislation providing for the Government function was phased out. Now there is talk about phasing it back in but with a different face, and I think it is important that we examine how best we can support an entity to deal with technological assessment and to do it in a way that is going to be accepted and one that we can promote the issue of the quality of medical care. We also want to maintain access and we also want to be very sensitive to the costs, not only from the Federal budget standpoint but also the impact to businesses, insurance premiums, and also the individual.

At this point in the record I shall insert a statement of the chairman, Senator Hatch. Senator Thurmond and Senator Kennedy will also supply statements for insertion.

[Statements of Senators Hatch, Thurmond, and Kennedy follow:]

STATEMENT OF SENATOR ORRIN HATCH, UTAH

Today we are holding full Labor and Human Resources Committee hearings to consider one of the important factors in the high cost of health care—that is, how we can better determine what kinds of medical services should be paid for by the Medicare and Medicaid programs. The process of considering what health services, diagnostic tests and therapeutic procedures are cost-effective and beneficial, is known as "technology assessment," and is currently conducted in the National Center for Health Services Research and the Health Care Financing Administration. However, there are many who feel that insufficient attention has been paid to evaluating just what we actually pay for in the name of health care services.

These hearings will give us an opportunity to learn more about what has been done and what we are now doing, and to consider proposals to improve our ability to direct public funds to purchase effective and economic health care services. I believe this is a critical issue during this time when health cost increases threaten the viability of the Medicare Trust fund. I look forward to the testimony of our expert witnesses.

STATEMENT BY SENATOR STROM THURMOND (R-S.C.) BEFORE THE LABOR AND HUMAN RESOURCES COMMITTEE REFERENCE HEARING ON HEALTH CARE TECHNOLOGY ASSESSMENT, ROOM 430, DIRKSEN SENATE OFFICE BUILDING. THURSDAY, JUNE 7, 1984, 9:30 A.M.

MR. CHAIRMAN:

It is a pleasure to be here today to receive testimony on health care technology assessment.

I want to commend you, Mr. Chairman, for the excellent job that you do in focusing the attention of this Committee on the Nation's most important health care issues.

The proper assessment of health care technologies, I believe, is essential if we are to achieve the most effective operation of our health care system. These technologies -- which have been broadly defined to include drugs, devices, medical or surgical procedures, and the knowledge necessary for their application -- are critical to virtually all segments of the health care industry.

However, there appears to be some question as to the effectiveness of health care assessment today and in the past.

Mr. Chairman, I am hopeful that through this hearing we will learn more about how the assessment of health care technology might be improved in our country. We have a distinguished group of witnesses with us and I look forward to their testimony.

STATEMENT OF SENATOR EDWARD M. KENNEDY ON
HEALTH CARE TECHNOLOGY ASSESSMENT

I am pleased that the Congress is re-examining the issue of health care technology assessment. In 1978, when I chaired the Health Subcommittee of this Committee, we conducted hearings that led to the passage of legislation establishing the National Center for Health Care Technology. Those hearings demonstrated conclusively the national need for a comprehensive, expanded, national technology assessment effort. Hearings conducted on the House side reached a similar conclusion. As the House report stated, "There is an emerging consensus . . . that many technologies have been widely adopted into medical practice in the face of disturbingly scanty information about their health benefits, clinical risks, cost effectiveness, and side effects. In addition, the use of some technologies persists long after it becomes evident that these technologies are of marginal utility, outmoded, and even harmful."

Although the current Administration forced the termination of the National Center in 1981, those findings are as true today as when the National Center was established. Dr. Arnold Relman, the distinguished editor of the New England Journal of Medicine, recently testified that "fifteen to twenty percent of all the tests, procedures, drugs and devices employed in the diagnosis and treatment of disease . . . are not worth the money we spend on them. They are either of no value, they are redundant and add little or nothing to less expensive technologies already in use or, in a few cases, may actually be harmful."

Dr. John Wennberg of Dartmouth has studied elective surgery on the elderly and found that, based solely on where patients live, they may be three or four times more likely to undergo prostatectomy for benign prostatic hypertrophy, or lens extraction for cateract. As Dr. John Bunker of Stanford recently testified, "The symptoms of a small or moderately enlarged prostate are widespread in men over the age of 65. The risks of surgery is a matter over which urologic surgeons differ widely. Much the same scenario can be painted for cataracts and their surgical correction, and for a host of other condictions and therapies."

Clearly, using the prostate surgery example, either some surgeons are performing far too many unnecessary and dangerous operations or other surgeons are failing to recommend surgery when it is necessary and desirable.

Clinicians want to provide their patients with the best medical treatment available. But in the absence of controlled, scientific assessment of safety and efficacy, much of medical practice must remain based on custom and intuition.

As. Dr. Seymour Perry of the Georgetown University Medical Center recently stated, "the majority of diagnostic devices and therapeutic procedures currently used in the practice of medicine have never been subjected to careful evaluation." A 1978 report of the Office of Technology Assessment estimated that only 10 to 20 percent of all procedures in medical practice had been subjected to controlled evaluation.

This situation serves neither the patients, the physicians, nor our society well. It results in needless risk, illness, and suffering and further inflates our Nation's already swollen medical bill.

During its brief life, the National Center demonstrated the utility of systematic technology assessment. The Center studied seventy-five technologies for the purposes of Medicare reimbursement and found that 40% were ineffective or without evidence of benefit. Evaluations by Harvard and UCLA Schools of Public Health showed that the Center's recommendations concerning only six technologies saved Medicare $100 to $200 million a year.

Even with the demise of the National Center, activity in the technology assessment area continues. According to Dr. Perry, there are at least 45 organizations involved in technology assessment. But the amount of resources devoted to that endeavor are tiny considering the need and potential benefits. The largest single investment in medical technology assessment is the National Institute of Health's clinical trials program, but this program accounts for less than 4% of the NIH budget, about $150 million a year, and NIH expenditures for clinical trials are actually at a lower level than they were in 1980. This expenditure of $150 million for systematic clinical assessment can be contrasted to the more than $9 billion a year the Nation spends on health research and development.

Earlier this year, I introduced an Omnibus Health Reauthorization bill, S. 2452, which was co-sponsored by all the other Democratic members of this Committee. S. 2452 included a provision which would have re-established the National Center of Health Care Technology Assessment. I am not wedded to that organizational form, and I hope that based on these hearings, Senator Quayle and I and other interested members of this

Committee will be able to work out a legislative proposal that will meet the national need for health technology assessment.

In my view, whatever organizational form is devised must meet the following criteria:

-- It must promote interchange and coordination among the organizations engaged in technology assessment to avoid needless duplication;

-- It must provide a mechanism for setting technology assessment priorities, so that limited assessment resources can be used most effectively;

-- It must encourage dissemination of the results of technology assessment so that practitioners and patients can benefit from the most current research.

-- It must provide authoritative guidance for public and private insurers needing to make decisions on insurance coverage;

-- It must be responsive to the needs of both the public and private sector; and

-- It must be provided adequate resources to meet our national need for technology assessment. In my judgement this last criteria means that there must be a substantially increased commitment of Federal resources to this activity, although the Federal government should not be the exclusive source of funding.

I look forward to the guidance of our expert witnesses on this important topic.

Senator **Quayle**. Our first witness today is Dr. Brandt, who is Assistant Secretary for Health and Human Services. He is accompanied, I believe, by Dr. John Marshall, the Director of the National Center for Health Services Research. Dr. Brandt is well known to all of us, has been before this committee numerous times. He needs no introduction so, Dr. Brandt, welcome back and proceed at your will.

STATEMENT OF EDWARD N. BRANDT, MD., ASSISTANT SECRETARY OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY JOHN MARSHALL, DIRECTOR, NATIONAL CENTER FOR HEALTH SERVICES RESEARCH

Dr. **Brandt**. Thank you very much, Mr. Chairman. It is a pleasure to appear before you today to discuss Public Health Service activities in medical technology assessment.

Let me preface my remarks this morning with a brief summary of the primary responsibilities of the National Center for Health Services Research. It is important to establish that there must be a link between medical technology assessment and health care delivery research. Medical technologies cannot be evaluated effectively unless they are examined within the environment in which they are used.

It is also important early on to recognize that there are a number of different definitions of technology. In my own mind the term "technology" includes not only the drug, device, or medical procedure under consideration, but also the knowledge and professional competence needed to apply that drug, device, or procedure safely and effectively on behalf of patient care. The facilities, personnel, and health delivery systems needed to deploy complex medical procedures have too often escaped consideration in the assessment process.

It is the study of these systems that health services research is all about. The NCHSR is the focal point within the Federal Government for research on the health care delivery system. It supports both an extramural research grant program and an intramural research program. One of its more popular and better known activities is the User Liaison Program, through which the NCHSR provides timely research results, written to meet the real time problem-solving requirements of both State and local officials.

Within the National Center, the Office of Health Technology Assessment is responsible for providing Public Health Service advice to the Health Care Financing Administration with respect to medicare coverage of medical technologies that are either not presently covered or that may no longer be considered appropriate. In my full statement, Mr. Chairman, I have outlined the process that we follow in accomplishing that advice to HCFA.

Technology assessment within the Public Health Service, however, includes much more than providing advice to HCFA on medicare coverage issues. Activities include primary data collection, secondary data analysis and synthesis, the development and continued evaluation of methodologies, and information dissemination. I have given a summary of each of those in the complete statement.

I believe the Public Health Service provides valuable services in three areas: first, in primary data collection for use by others doing technology assessment; second, in the development, validation, and continued evaluation of methods for assessing technology; and, three, in continuing to provide HCFA with assessments of health care technology. These assessment activities, however, are circumscribed and should be supplemented—indeed, must be supplemented—by professional associations and others.

Over the past year we have been reevaluating the role of the Public Health Service in technology assessment. Questions we have asked are, one, should we assume full responsibility for technology assessment in this country? We have rejected that responsibility. Should we assume greater regulatory authority over the use of new technologies? Again, we think not.

In answer to that second question, the Public Health Service is not in a position to make decisions about who should receive a particular technology, who should provide that technology or where that technology should be provided. It is our responsibility to provide the best clinical and scientific information about new medical technologies to HCFA and to the public. We have that responsibility because of the need for the Federal Government to maintain responsible stewardship over the medicare trust fund.

We also have a responsibility to administer faithfully the regulatory laws over drugs and devices but, beyond that, I believe that it is the responsibility of the private sector to make its own decisions about the purchase and use of new technology. In my judgment, technology assessment would be best served by some private/public partnership.

We have been working with the Institute of Medicine with respect to a plan for a consortium within the private sector to accomplish this assessment. Such a partnership would take advantage of important work already being done by such groups as the American College of Physicians, the AMA, the American College of Cardiology—all of whom you will hear from later today. The continued participation of these organizations in technology assessment is critical. We, the Public Health Service, cannot and should not duplicate the valuable and important role that these groups play. A heavy handed Federal role, whether perceived or real, has not worked in the past and would not be accepted in the future.

We have also reviewed your bill, Senator Quayle, S. 2504, and we have pointed out some of our concerns about that bill in our testimony. In particular, we would point out to you that although the bill was very specific in some instances, it does not provide adequate guidance in others. For example, there is no mention of who would be empowered to direct the Institute to examine a particular technology.

On the basis of the reasons outlined in the testimony, the administration does not support the approach offered by S. 2504. If it is determined that legislation for technology assessment is to be pursued, we would prefer the general approach contained in H.R. 5496, which emphasizes more strongly the role of the NCHSR.

That concludes my statement, Mr. Chairman. We will be happy to answer any questions that you may have.

[The prepared statement of Dr. Brandt follows:]

STATEMENT OF

EDWARD N. BRANDT, JR., M.D.
ASSISTANT SECRETARY FOR HEALTH
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman and Members of the Committee

It is a pleasure to appear before you today to discuss the Public Health Service (PHS) activities in medical technology assessment. I am accompanied by the Director of the National Center for Health Services Research (NCHSR), Dr. John Marshall.

I would like to preface my remarks this morning with a brief summary of the primary responsibilities of NCHSR. Such a summary is important because of the link that must exist between medical technology assessment and health care delivery research. Medical technologies cannot be evaluated effectively unless they are examined within the environment in which they are used. I should caution, however, that any description of an agency's role in technology assessment is complicated by the many different definitions of "technology." In my own mind, the term "technology" includes not only the drug, device, or medical procedure under consideration, but also the knowledge and professional competence needed to apply that drug, device or procedure safely and effectively on behalf of patient care. The facilities, personnel and health delivery systems needed to deploy complex medical procedures have too often escaped consideration in the assessment. The study of these systems is exactly what health services research is all about.

NCHSR is the focal point within the Federal government for research on the health care delivery system. It provides information that is used to improve the effectiveness, efficiency and distribution of health care services in this country. The Center supports an extramural research grant program based on peer review of investigator-initiated research. It seeks to develop the knowledge base for future policies, as it did for example in the developmental work on many key features of our modern health care delivery system.

NCHSR also conducts an intramural research program that provides the basis for estimating the cost of medical care, the extent of insurance coverage, and the effects of treating employer provided health coverage as a non-taxed benefit. NCHSR has also developed methods for predicting the need for long-term care. The Hospital Cost Utilization Project data base will prove useful in the Department's evaluation of implementation of prospective payment and its effects over the next five years.

Through its User Liaison Program, NCHSR provides timely research results written to meet the real-time problem solving requirements of State and local officials.

Within NCHSR, the Office of Health Technology Assessment (OHTA) is responsible for providing PHS advice to HCFA with respect to Medicare coverage of medical technologies that are either not presently covered or that may no longer be considered appropriate. Briefly stated, the process works as follows: When inquiries regarding the coverage of medical technologies cannot be resolved by Medicare contractors and are forwarded to HCFA, a physicians' panel, established by HCFA, reviews the issue. This panel includes a representative from OHTA. The panel may make a determination regarding the coverage of the specific medical technology, or if the panel determines that a formal assessment of the safety and efficacy of that technology is required, it may refer the question to NCHSR. OHTA staff consult with appropriate scientists and experts from PHS agencies, review the available scientific literature, solicit views from relevant medical speciality and sub-specialty groups, and provide an opportunity for the developers of the technology to supply additional information they wish to have considered. A preliminary assessment document is prepared and sent to PHS agencies for comment. The final assessment is then forwarded to HCFA which is responsible for the decision as to coverage.

Once the actual coverage decision is made, HCFA notifies its contractors and fiscal intermediaries of its decision by instructions in manuals. State Medicaid agencies also refer to the HCFA manuals because some agencies base their determination for coverage on HCFA's position. In addition, NCHSR disseminates its assessment to insurance companies and other interested groups. OHTA assessments are also reported in the Annual Technology Guide published by the American Hospital Association.

Technology assessment within the PHS includes much more than providing advice to HCFA on Medicare coverage issues. Activities include primary data collection, secondary data analysis and synthesis, development and continued evaluation of methodologies, and information dissemination. These activities are summarized below:

- Primary Data Collection: These activities are conducted and supported primarily through research activities of NIH and ADAMHA, in particular through the support of clinical trials. NCHSR does not support clinical trials but does support technology assessment research including the assessment of specific technologies.

- Secondary Data Analysis and Synthesis: These activities are conducted primarily by the NCHSR in its support of health services research and in the development of guidance or recommendations regarding Medicare coverage issues, by the NIH in its consensus development conferences, and by FDA in the regulation of drugs and devices.

- Development and Continued Evaluation of Methodologies: NCHSR has primary responsibility to conduct research into refining the methods of assessing technologies.

- Information Dissemination: All PHS agencies engage in information dissemination, the largest single institution with this function being the National Library of Medicine.

I believe that the PHS provides valuable services in three areas: (1) in primary data collection for use by others doing technology assessment; (2) in the development, validation andcontinued evaluation of methods for assessing technologies; and (3) in continuing to provide HCFA with assessments of health care technologies. The technology assessment activities that I just described are rather circumscribed, however, and should be supplemented by professional associations and others.

Over the last year we have been reevaluating what the role of the PHS should be in technology assessment. Questions we have asked are: Should we assume full responsibility for technology assessment in this country? I think not. Should we assume greater regulatory authority over the use of new technologies? Again, I think not.

In response to the first question, new information is being developed at too great a pace and over too wide a spectrum of clinical medicine to leave the assessment process solely to the Federal Government. I also believe that the medical profession, manufacturers and third-party private payers also need to participate.

In answer to the second question, the PHS is not in a position to make decisions about who should receive a particular technology, or who should provide that technology, or where the technology should be provided. It is our responsibility to provide the best clinical and scientific information about new medical technologies to HCFA and to the public. We have that responsibility because of the need for the Federal Government to maintain a responsible stewardship over the Medicare trust fund. We also have a responsibility to administer faithfully the regulatory laws over drugs and devices. Beyond that, I believe that it the responsibility of the private sector to make its own decisions about the purchase and use of new technologies.

I believe technology assessment in this country would be best served by a private-public partnership. We have worked with the Institute of Medicine with respect to a plan for a consortium within the private sector to assess medical technologies. I have met with the President of the IOM to discuss possible implementation of the recommendations contained in its final report, and continue to be optimistic that such a consortium will emerge. We look forward to cooperating in such a venture.

A public-private partnership in technology assessment would also take advantage of the important work already being done by such groups as the American College of Physicians, American Medical Association, and the the American College of Cardiology. The continued participation of these organizations in technology assessment is critical. The PHS cannot and should not duplicate the valuable and important role of these groups. A heavy-handed Federal role, whether perceived or real, has not worked in the past and it will not be accepted for the future.

Mr. Chairman, S. 2504 would establish an Institute for Health Care Technology Assessment, within the private sector, to promote the development and application of approved technologies, as well as promote the elimination of obsolete or inappropriate technologies. Major responsibilities of the Institute would be to serve as a clearinghouse, collect and analyze data and make recommendations concerning specific health care technologies, stimulate, coordinate and undertake health care technology assessments, identify needs in the assessment of health care technologies, develop and evaluate criteria and methodologies for health care technology assessment, and provide education and training programs in the use of health care technology assessment methodologies and results. A Board of Directors would be selected from organizations representing health providers, manufacturers, third party payers, and consumer groups. Finally, the bill would provide for a $2 million line of credit from HHS to remain available for seven years.

I would like to take the opportunity to point out several provisions of the bill that are of major concern to me. Overall, the bill is very specific in some cases, but does not provide adequate guidance in other areas. An example of this latter problem is that there is no mention of who would be empowered to direct the Institute to examine a particular technology.

Further, it is unclear what the Department's financial involvement in this endeavor would be and if the credit extended is to be repaid at some point in time, where the

Institute would derive the revenue to do this. We are opposed to a line credit approach such as proposed in the bill since it distorts the normal appropriations process. Legislation leading to Federal matching of funds is inappropriate.

I am also concerned about the authority for the Institute to determine which devices, drugs or other treatments are obsolete or inappropriate. To carry this authority beyond disseminating information about medical technologies, will quickly embroil the Institute in counterproductive controversies that may well prove destructive. We know from past experience that industry and providers of care will not accept any entity that has proscriptive authority over the appropriate uses of specific technologies.

Another concern relates to the composition of the proposed Board of Directors as called for in the bill. I believe that it is too specific and would preclude membership on the Board of persons with a legitimate interest in participating. Second, statutory requirements specifying board membership might well conflict with the governance requirements of university-based or other non-profit organizations which could effectively develop the Institute. We have also found that it is very important that persons on this kind of board must represent a balance of viewpoints--not only those with a financial interest in medical technologies, but also persons with scientific and medical competence.

For these reasons, we do support the approach offered by S. 2504. If it is determined that legislation for technology assessment will be pursued, we would prefer the general approach contained in H.R. 5496 which emphasizes the role of the NCHSR. That concludes my statement, Mr. Chairman. I would be happy to answer any questions you may have.

Senator **Quayle**. Dr. Brandt, I certainly agree with some of the themes that you noted in your statement—on page 7, where you said the PHS cannot and should not duplicate the valuable and important role of these groups, other groups that had been involved in technology assessment; also, where you indicated and stated that a heavyhanded Federal role, whether perceived or real, has not worked in the past and it will not be accepted in the future. I concur with that.

My interest, if you look at the approaches on how we are going to get this public/private partnership, you find basically the two approaches. The Senate approach and the House approach. The Senate approach is far more geared toward the private—as a matter of fact, almost in total. The 12 board members, are all from the private sector. The Government's role is initially extending grant or a line of credit, plus ex-officio representation of OTA, and also the Secretary of HHS. We left a lot of flexibility because we are not exactly sure where that board ought to go. I notice that you talked about the lack of adequate guidance. Well, that was done purposefully. We didn't want to give a lot of guidance because we didn't want to get into the heavyhandedness that you talked about in your statement.

I think we need, however, a little bit of amplification on how this public/private ought to work. The House bill goes much more toward the public aspect. It has the private participation in there but there is much more involvement by the public sector as, for example, with the actual appointments. I don't think you want to go back and recreate the Center but in some respects I think that particular approach does. In fact, with only a few changes, it goes back to where we were before, in 1981, before we phased out the center because of political considerations—one being budget, others being effectiveness and whether it was really useful or not.

Therefore, I wonder if we might get into a discussion on how this public/private participation is really going to take place. Let me just say this at the outset: I think if you look at trying to get maybe an equal balance, even, that ours is very slanted and, I think, for good reason slanted to the private sector. I think that they've got to be involved. They are the ones that developed the technology. They are the ones that will implement it in most cases. We oversee it. We obviously pay for some of it through Government programs. However, I wonder if you might be able to expand a little bit on this, how we are going to get this public/private participation?

Dr. **Brandt**. Let me say at the beginning, Senator, that I would commend you for this hearing as well as bringing this issue up for discussion and debate because I think it is important. It seems to me that there is a whole continuum of issues related to technology assessment.

First, to begin with, the development of technology itself is largely, hopefully, based upon good, solid basic research which the Public Health Service has supported traditionally through the NIH and ADAMHA and other programs and would continue to support and ought to continue to support. Second is the aspect of attempting to make sure that new technology, as it comes down the pike, is in fact integrated into the whole health care delivery system. I think perhaps the best example of that is the whole immunization issue, where it has been necessary to do the kind of research and do the kind of work that made it possible in the late seventies or midseventies to initiate a massive immunization program in this country that has worked very well

Then, third is the issue of looking at specific aspects of technology and trying to determine whether or not that technology is of value on the one hand and is of more or less value than comparable technologies that may already be available. We agree completely that that is something that requires a private/public kind of relationship. In the first place, the Federal Government has to be involved because we are paying for a lot of medical care through medicare and medicaid, Indian Health Service, VA, Department of Defense, and so forth. The Federal Government is investing a great deal of money in the payment for health care and has to be concerned and interested and a full participant in any kind of technology assessment that takes place, so I don't see any way for the Federal Government to get out of this completely because of, if nothing else, our own vested interest in the problem.

On the other hand, it is also very clear that the organizations that are currently doing this—the AMA, the American College of Physicians, the American College of Cardiology, a number of others that are involved to a greater or lesser extent—are the experts. They are the people who are out there on the front line. They are the ones that are delivering the health care. They are the ones that must also be involved in the assessment.

I think the fundamental issue is, how do we bring everybody together, including the third-party payers who should have a great deal of interest, the professional groups, and the scientific community, into some sort of relationship. That is why we worked with the Institute of Medicine, to get them to pull together a committee to draft this report. Now whether or not you agree with or like the report, I think it is step one toward bringing everybody together to begin to debate the issues.

The House bill, as you know, provided specific authority to award grant money to such an entity, such a private entity, for purposes of startup costs and other kinds of things, to get it underway, so I don't think they totally ignored it. The important principle, in my judgment, and the one that we have to keep in front of us, is that this has to be some sort of private entity that has full access to all of the private organizations that have a commitment, and that also involves the Federal Government.

I think that progress is being made toward getting everyone to work together and to begin to address this issue, and I think this hearing today will help elucidate further some of the things that we need to know.

Senator QUAYLE. Let me take a couple of those thoughts. First of all, the report of IOM that you said is a good first step. We basically, in trying to give some guidance but not restricting the Institute too much, took I think five of those elements right out of the study and report because we also felt that that was a good step forward.

Dr. BRANDT. Yes.

Senator QUAYLE. I think that our approach is the same as your approach, in that we want to figure out an entity to bring everybody together, we don't disagree on that. We don't disagree that the objectives that were laid out in the IOM report are solid. It ought to be followed up. I do not disagree that we ought to figure out the best way to get everybody together.

Now, my question is, how do we do that? That's where it comes down to, to a matter of detail. You used the words that the Federal Government ought to be a "full participant." I would presume you would say that the private sector should also be a full participant, too.

Dr. **Brandt**. Well, I meant to imply along with all the other participants, obviously. I guess what I am saying is that the Federal Government has to live up to its own responsibility in this issue. Along with all the others that I talked about, one of its responsibility is clearly to provide high quality medical care or to see that high quality medical care is provided to its beneficiaries. That means that we must participate in any kind of entity that exists, but it should not be a Federal entity. I mean, we are not the only player in this game, by any stretch.

Senator **Quayle**. OK, and I also believe that you should be a full participant and the private sector should be a full participant. My question is in trying to get this balanced participation between the public and private. I think you would agree with me that we don't want to go back and sort of recreate the Center for Health Care——

Dr. **Brandt**. Health Care Technology.

Senator **Quayle**. Thank you. The Center for Health Care Technology that was phased out in 1981. I don't think we want to go back and recreate that.

Dr. **Brandt**. Absolutely not.

Senator **Quayle**. Absolutely not. OK, we don't want to do that because of the problems you had, the political problems. It was just basically a Government program. The private input to that was not taken seriously or as being meaningful, so we don't want to go back to the center approach. We want to come up with a new, a more balanced approach, and we do agree, I think, that we need some entity to perform an additional role and responsibility for technology assessment. Is that fair?

Dr. **Brandt**. Yes, sir, that is certainly fair.

Senator **Quayle**. Now it seems to me that perhaps the dispute, if you take the Senate approach versus the House approach—and you can answer this—is basically on the selection of the board? You used the statement that in the Senate approach, that there wasn't adequate guidance. I presume that you feel there is more guidance in the House approach.

I wonder if you might delineate where there are differences because I think that there are also three or four objectives we just outlined, where there is no disagreement.

Dr. **Brandt**. Correct.

Senator **Quayle**. What we are coming down to is forming this entity to achieve the philosophical or principled ideas that we have advanced thus far. I wonder, maybe you can outline for me how this entity could be improved over the entity we presently have in the original draft of the Senate bill.

Dr. **Brandt**. First I think that the important principle is that technology assessment as an activity not be divorced from—this may be too strong a word—not get too far afield from health services research. I think that one of the problems with the National Center for Health Care Technology was the fact that it ignored the environment in which technology was going to be used. That is, it looked at technology kind of de novo and separate, rather than to try to put it into the total perspective, so I think that we have to keep the technology assessment activity within the total framework of health services research, evaluation, et cetera.

Second is that I would, my own druthers would be to say to the private organizations that are out there—many of which, again, you will be hearing from today, including third party payers and so forth—that they ought to get together and come in to the Federal Government with a proposal and that clearly the Federal Government ought to invest in some entity for this purpose. I don't have any problems with that, but we need to come in with something that will allow us to determine the extent to which the Federal Government will participate as a partner. We could, through the National Center for Health Services Research, begin to provide some kind of funding that would allow it to get started. That is, I guess, the basic approach that we would favor.

Senator **Quayle**. OK. If, in fact, the private sector could get together a consortium as such of people that are dealing in the total environment of health services or the health delivery system, payers, et cetera could come together and say, "OK, here is our working group. Here is the board of directors that we would like to create," then you are indicating that you would be willing to take a look at that and perhaps see what you could do with the National Center for Health Services Research to become a partner. Is that what you're saying?

Dr. **Brandt**. Well, I think technically it would be HCFA that would probably be the principal partner but yes, that is fundamentally what I am saying. One of the considerations that I think we have to look into, is that one whole mass of talent out there has been kind of lost in much of the deliberation that is the university system. There are a number of universities around the country that certainly have the capacity or, with minimal change, could develop the capacity to perform this kind of function—bringing in, again, all of these other organizations through a whole route of administrative and other mechanisms to accomplish this activity, so that I don't want to exclude them from consideration. That is one reason why we would prefer leaving the nature of that private/public activity somewhat vague, until we see what kinds of organizations it is possible to put together and come in and address this problem.

Senator **Quayle**. However, to get these organizations together—and perhaps the universities should be more well represented than what the Senate approach has outlined—but to get these groups together, don't you think that there is some initial effort that ought to be made by us, meaning the Congress and the administration, to sort of get this off the ground? We have been discussing technology assessment. It is certainly not a new issue. It has been around. You have referred a number of times to the various groups that are already doing it, and I have found that if there isn't some additional element superimposed upon the various groups out there—that says, "Come on, people, we're going to get together and try to work this out—that the tendency is for them to sort of go their own way. One group says: "Well, we've got perfectly good technology assessmant. We don't need any others. Do it our way and it will be fine." That's not what we're trying to do because we want to get back to your words and what I believe and detect, and that is—how do we bring everybody together. That was our desire in this Institute and I am open to suggestions on how we can expand or contract the makeup of the board of directors, how it is appointed, et cetera. This is rough. It's the first shot out of the box. That's why we are having these hearings today.

However, the way I hear you is that the approach that we took in trying to grapple with this issue is certainly not counter to what we have done; that this was a means to try to get these various groups together. You know, IOM took the first step and we took a lot of what they said in their report. Don't you think that we are going to have to take the next step in order to bring everybody together?

Dr. **Brandt**. Well, let me just try to describe for you briefly what we have done. In the first place, we did participate with the IOM activity, including paying what was determined by them to be our fair share of the cost of that activity, and we I think recognized that although this is an IOM document, we did participate.

Second, I think we have recently reorganized the Technology Coordinating Committee, and I think I am going to ask Dr. Marshall if he can give you a summary of what that committee is doing and who is on it and that sort of thing.

Mr. **Marshall**. Yes. Basically, under the National Center for Health Care Technology there was an advisory council, but then there also was internal to the department a Technology Coordinating Committee. This committee was intended as a body to try to cross not just the Public Health Service and the Department but across all organizational elements that were involved with technology, including the Veterans' Administration and the Defense Department. It meets periodically to discuss issues and to try to coordinate approaches so that folks were doing things that were complementary rather than duplicative.

We decided several months ago that one of the things we should do as we looked at the IOM report and as we considered the various congressional actions that were pending, was to establish that committee as a revitalized, more broadly based organization. In fact, we did that and yesterday had the first meeting of the group. What we did was to add to the Federal membership the participation of organizations that have a great deal of interest in these issues. In fact, it was sort of a preliminary to today's meeting because we had the first meeting yesterday afternoon, and I see that a number of the witnesses were people who represented their organizations at that meeting yesterday.

What we did was added representation from the Health Insurance Association of America; the Blue Cross-Blue Shield; the Health Industry Manufacturers Association; the National Electrical Manufacturers Association, the part that deals with much of the medical technology development; the American Medical Association; and several other groups. We have established subcommittees that have been charged with specific tasks. One is a committee that will begin to look at the question of imaging techniques such as nuclear magnetic resonance and other imaging techniques that are coming along that hold a great deal of promise but that also are clearly going to be very expensive, and where we have a responsibility and are ourselves working on an assessment for that. We will be using that subcommittee as a way of coordinating what a variety of groups are doing in that area so that 9 to 12 months from now, when we are prepared to go to the Health Care Financing Administration with some advice for coverage, it clearly will be advice that recognizes what the activities are of other people in those private sector groups.

We have also established a subcommittee that will be dealing with the methodologies that we need for the future for looking at assessment of technology, including some cost benefit analysis, which is an area that is very weak right now. The main task, I believe, of that subcommittee will be to try to develop for us a research agenda of activities that are promoting the development of methodology for technology assessment, that can be funded through our extramural research grant program.

Finally, we agreed yesterday as a result of the suggestions of largely the non-Federal members of that group, to establish a task force that in 60 days will take a look at what our current technology assessment process is from the perspective of the people who develop and merchandise the technologies, and try to look at what advice they have for how we might improve our process for getting advice to the Health Care Financing Administration in a more timely manner.

That kind of activity, I think, represents the sort of functional relationships that we need to see developed. As I was thinking about the question you asked Dr. Brandt about what the difference was, my reading of the House bill was that the committee had a clear-cut advisory role to the Government and to the industry, whereas my reading of the bill that we are discussing today almost suggests that the Council is more representative and that what is more the objective, is the representativeness of it rather than what its actual functions would be. While I understand it is useful to keep it somewhat non-specific at this point, it may be perceived in a way that would be quite different and that would then make it difficult to function effectively in the relationship with the Government, or at least with that part of the Government that has the responsibility for making coverage decisions.

Senator QUAYLE. Well, I can just tell you the intent was to leave it rather vague on what the functions and what the authority, et cetera, was going to be, because I have always been a great believer that if you are going to ask for a contribution of time from the private sector or from anybody and also ask for money, that you shouldn't be too proscriptive on what their function ought to be. The board of directors will contain capable men and women that can sit down and they can hammer out their decisions and the directions with the participation of the Secretary of HHS and OTA. Maybe—and I think what you are saying when you talked about this interrelation group is that you are also trying to cultivate more of this private involvement—you are a little bit fearful that if you do not involve them, they would just sort of go their own way and their activities would be completely private and lack responsiveness or communication with the public officials. I certainly don't want that. That would be the extreme on the other side. That would not be workable, so I am not trying to get there. Is this what you are sort of saying to me today, that you fear this a little bit?

Dr. **Brandt**. No, I don't. I am not really all that concerned about that aspect of it, Senator, because I think if that were much of a risk, we wouldn't be having a hearing today. There would be a technology assessment activity going on out there in the private sector that would satisfy all of our needs.

The only point that I am trying to make is that I think that the reason for continuing to push the public part of the public/private partnership is that the Federal Government also has a legitimate and major interest in the outcome of technology assessment.

Senator **Quayle**. I do not dispute that.

Dr. **Brandt**. Furthermore, we have a feedback loop that I think is important because as you carry out technology assessment, you also identify deficiencies. Those kinds of deficiencies have to be fed back into the research priority aspects that we are also responsible for, so all I am really trying to say is that the Federal Government has a legitimate interest in and an absolute responsibility to participate in this. I am not afraid of private activity and would have full confidence, as a matter of fact, that they would meet all of our needs. However, at the same time I think that is kind of in a sense an abrogation, if you will, of some of our own responsibilities.

Senator **Quayle**. What major change except for the line of credit aspect would you recommend in the Senate approach on the formation of it? I am looking at just the formation and the way that it's set up. What kind of major changes would you suggest to make this more palatable to your thinking?

Dr. **Brandt**. The line of credit funding thing is not something that I am competent to talk about.

Senator **Quayle**. Yes, let's just skip over that. That's a minor thing, anyway.

Dr. **Brandt**. Well, I think again that the goal or the major thing that we would like to see is much closer ties with the total technology assessment activities that are carried out under the National Center for Health Services Research. I think that's our major concern and we will be pleased to submit to you some additional details, if you would like.

Senator **Quayle**. OK. That is your major concern, then, and if we could correct that—particularly the working group that Dr. Marshall talked about putting together is very representative of what we have put into our institute—I think it is just a matter of some adjustments that may be necessary. We will be more than happy, after we finish with our other witnesses, to sit down with you and maybe come up with something that you would deem to be more workable than it presently is in the law.

Thank you very much, Dr. Brandt and Dr. Marshall. We do certainly look forward to working with you.

Dr. **Brandt**. Thank you, Senator.

Senator QUAYLE. Senator Kennedy has some written questions for both of you that will be submitted to the record for your response. Also, I have a statement from Senator Kennedy that will be inserted in the record immediately following my opening statement and before Dr. Brandt's statement. I am also informed that Senator Hatch will have some written questions for Dr. Brandt and Dr. Marshall and others, and Senator Thurmond will have a statement that will be inserted in the record appropriately.

The next panel is Donald Young, Lawrence C. Morris, and Ian Rolland. Also, I understand that Dr. Leaf would like to be on this panel because he has a scheduling problem, so Dr. Leaf may join that panel as well.

Gentlemen, I am going to ask if in order to expedite things, you might restrict your opening statement to 5 minutes if at all possible. If you can summarize in 5 minutes, it would be most helpful to all of us so we can get into some of the questions. I will have this clock going and you can watch it. I won't slam the gavel down or anything, but when it turns to red that means that you are in the danger zone or you have passed the danger zone and it is about ready to go off.

Dr. Young.

STATEMENT OF DR. DONALD YOUNG, EXECUTIVE DIRECTOR, PROSPECTIVE PAYMENT ASSESSMENT COMMISSION, WASHINGTON, DC

Dr. YOUNG. Good morning, Mr. Chairman. I am Donald Young, executive director of the Prospective Payment Assessment Commission. I am pleased to testify before you today to describe the responsibilities and activities of the commission, often called ProPAC, particularly as they relate to technology assessment.

As you know, ProPAC was established under the Social Security Act of 1983 as an independent commission to advise and assist the Congress and the Secretary of the Department of Health and Human Services in maintaining and updating the new Medicare prospective payment system.

The formal responsibilities of ProPAC are mandated in the law, with the work of the Commission centered in two primary areas: First, recommending annually to the Secretary of HHS the appropriate percentage change in the payments made under medicare for inpatient hospital care; and, second, consulting with and recommending to the Secretary and reporting to the Congress, necessary changes in the diagnosis-related groups, including advice about establishing new DRG's, modifying existing DRG's, and changing the relative weights among the DRG's. Our first report on these subjects is due April 1, 1985.

The 15-member Commission, appointed by the Director of the Office of Technology Assessment, is assisted in its work by a staff of not more than 25. Provision is also made in the law to enable the commission to utilize and collect existing information where possible and to contract for new data and carry out analyses necessary to make well informed recommendations if needed. The Commission and its staff plan to utilize existing data and information from Government and nongovernment sources to the maximum extent possible. In areas where information is lacking, the Commission will use its statutory authority to award grants and contracts for data gathering and analytic studies that are clearly focused on its direct responsibilities.

In order to meet its responsibilities to keep the new prospective payment system accurate and up to date and to maintain appropriate financial incentives, the Commission will need to assess changes in the nature of hospital care, carefully reviewing changes in such areas as productivity, new and existing technologies, scientific advances, length of hospital stay, differing patterns of resource utilization, changes in nursing and other staffing patterns, and quality of care.

The changes occurring in medical- and hospital-services delivery must be identified and reflected in the DRG classification and weighting system and in the recommendations we are required to make regarding the appropriate update factor. Our findings may lead to adjustments needed because of new technologies which may be costly but quality enhancing or adjustments may be needed because an existing technology is becoming obsolete and its cost may exceed its value.

This work will require review of a great deal of information on systemwide changes in the provision of hospital services, as well as specific data on the nature of care being delivered, including information concerning scientific and technological advances. We will, therefore, need and have begun to solicit data from a large variety of public and private sources. We see ourselves primarily as users of information at this point but we are in the process of developing the capability to supplement existing information with our own data-gathering activities, evaluation, and assessment when necessary.

Clearly our information needs and our work will focus on changes in the delivery of hospital services to medicare patients. Related to this, however, we will be examining changes in the site of service delivery. For example, the movement of certain surgical procedures from an inpatient to an outpatient setting is an important technological change which the Commission may wish to examine as part of its overall responsibilities.

The Commission believes there is need for additional efforts in the area of health-care technology-assessment, and we support the interests of this committee and others in the Congress in carefully examining ways to encourage technology assessment activities. We view technology assessment in a broad way—as assisting in better understanding of practices and procedures used in the care of patients, including considerations of safety, efficacy, alternative approaches to problems, and relative costs and benefits. The results of technology assessment will be valuable to many groups, including the commission, and in the long run should be a tool to help achieve the goal of cost-effective medical care of high quality.

Currently the commission and its staff are developing working relationships with other groups involved in technology assessment, as we wish to prevent any duplication or fragmentation of the efforts already ongoing in this area. We do believe, however, that the need for information is great and that the results of critical and thorough technology assessments can and should be used by both private and public decisionmakers who struggle with the challenge of providing high-quality care during a time of ever-increasing costs.

Our own information needs for the Commission will be focused, as I mentioned, to those related to hospital services for medicare patients. When these needs are not completely met with existing data, we will gather data and conduct assessments to supplement existing information to meet our specific needs. In any event, we anticipate that information generated for and used in Commission decisionmaking will be available to all parties who have an interest in the area, and we look forward to making a meaningful contribution to the field of technology assessment within the mandate of our responsibilities.

I will be pleased to answer any questions you may have.

Senator QUAYLE. Thank you very much, Dr. Young.

Mr. Morris.

STATEMENT OF LAWRENCE C. MORRIS, SENIOR VICE PRESIDENT, BLUE CROSS & BLUE SHIELD ASSOCIATION, CHICAGO, IL

Mr. MORRIS. Thank you, Mr. Chairman.

Representing the Blue Cross & Blue Shield Association, I am pleased to have an opportunity to present our views on the important subject of health-technology assessment. I would like to note at the outset that we do support the general approach that is embraced by S. 2504.

From our perspective, medical technology assessment has more than one component. An important one is the capacity of third-party payers to make technology assessments focused on payment and coverage issues; and, second, there is a need for a capacity on the part of the entire health-care industry—the provider, the consumer, and the payer—to assess medical technologies in terms of their effectiveness, safety, and in comparison to alternatives and longrun consequences of use.

With respect to third-party payers, we believe that every major payer has a responsibility and should have the capacity to determine whether and under what conditions it will pay for the application of medical technology. Obviously there are limits to the carrier's latitude, but there are also areas in which the carrier must have the ability to make judgments. It must also accommodate the needs and desires of its customers.

Our own organization has developed such a capacity, and we would support the authorization of adequate funding for a similar capacity within the Federal Government. We would leave to those who manage the medicare and medicaid programs, the selection of the organization and the structure best suited to their own needs.

We do believe strongly, though, that the Government's process of making technology-payment decisions should not be construed as a mandate to other, nongovernmental, third-party payers, and conversely we don't believe that coverage decisions by private payers should be construed as recommendations to the Government. Our own technology-assessment process is geared to respond to the requirements of Blue Cross and Blue Shield plans which are administering their contracts which govern the coverage quite closely. To help support this process, we have established an information network with a number of medical organizations, and also maintain close communication with governmental agencies which have interests in such activity. Staff from the Health Care Financing Administration and/or CHAMPUS frequently attend our meetings and participate in our discussions. The objective of this is to share information and to maintain a consistency, or at least an understanding of divergency between major payment programs.

Parenthetically, for several years in Dr. Young's previous position at HCFA, he was a frequent and very valued visitor at our meetings.

Another approach that we have employed is the Blue Cross & Blue Shield Association's medical necessity program. Since its inception in 1977, it has relied on scientific and medical technology guidance from more than 20 nationally prominent, very expert professional medical organizations. The program has three basic components: First, there is the procedures list, which deals with procedures that are considered outmoded or of dubious usefulness. We are pleased, incidentally, to note that S. 2504 does directly address the issue of obsolete procedures, which is something that certainly ought to be considered.

Second, there is a hospital-admission-test battery policy which has resulted in a steady decline in unnecessary hospital admission testing. Third, the current focus is on ancillary care guidelines, which are a series of guidelines addressing the inappropriate use of generally worthwhile modalities in ancillary services such as respiratory care, diagnostic imaging, cardiac care, and pathology services.

Now, in addition to the individual capacities of third-party payers, we believe that there is a critical need for a national entity to provide a continuing, thorough, longer range view of technology issues. Importantly, S. 2504 does recognize this need and makes some provision for Federal assistance in meeting it.

Now we would recommend that you consider providing Federal support in the form of a grant rather than a line of credit but, as you pointed out a few minutes ago, that is not fundamental to the basic concept. The information and evaluations that should flow from such an entity would serve many purposes. Those would include improving the quality of information upon which third party payers make their coverage decisions but, perhaps much more importantly, it would support the best possible clinical applications of the technology. The function should be to detect, follow, and support analyses of new technologies long before they become coverage issues. The central characteristics of such an entity must be competence and credibility.

We believe the need is less for an entity whose interests are focused on a single technology than for one which can, on a continuing basis, deal with a broad range of clinical development. The recent Institute of Medicine proposal to establish a consortium offers a useful vehicle upon which to build such an entity. We would be willing to contribute our share to such an enterprise.

Again, Mr. Chairman, noticing the red light, thank you for this opportunity. [Laughter.]

[The prepared statement of Mr. Morris and responses to questions submitted by Senators Grassley and Kennedy follow:]

TESTIMONY
OF THE
BLUE CROSS AND BLUE SHIELD ASSOCIATION
HEALTH CARE TECHNOLOGY ASSESSMENT
BEFORE THE
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

I am Lawrence C. Morris, Senior Vice President of the Blue Cross and Blue Shield Association. On behalf of our member Plans, I am pleased to have the opportunity to present our views on the important subject of health care technology assessment.

Before presenting our views on technology assessment, I would compliment you, Mr. Chairman, for recognizing the need for an independent Institute for Health Care Technology Assessment. We strongly support the establishment of such an Institute and I will elaborate on this later in my statement.

From our perspective, medical technology assessment has two components:

- Narrowly, the capacity of third-party payers to make technology assessments focused on payment coverage issues; and

- More broadly, the capacity of the entire health care industry — provider, consumer and payer — to assess medical technologies in terms of effectiveness, safety, comparison to alternatives and long run consequences.

Third Party Payers

We believe that every major payer has the responsibility, and should have the capacity, to determine whether and under what conditions it will pay for the application of medical technology. Obviously there are limits to the carrier's latitude. But there are also areas in which the carrier must be free not only to make its own judgments, but to accommodate the desires of its customers. Our organization has developed such a capacity, which I will describe later. Based on our experience, we would support the federal government's strengthening its own capacity related to Medicare, Medicaid and other federally financed health care programs. Therefore, we support the authorization of adequate funding for such a federal capacity. Those who manage the Medicare and Medicaid programs should select the organization and structure best designed to serve their needs, since those coverage decisions need to be responsive to the objectives and financial capacity of the buyer. But, the government's technology payment decisions should not be construed as necessarily affecting other (non-government) third-party payers. Similarly, we do not believe that such coverage decisions by private payers should be construed as recommendations to the government.

The Blue Cross and Blue Shield Association's technology assessment process is geared to respond to the requirements of Blue Cross and Blue Shield Plans. For Plans, the decision to pay or not to pay for a service depends upon contract provisions that specify the scope of benefits. This requires the designation of procedures as either generally accepted medical practice or experimental/investigative. Such designations often change with time, as the application of procedures evolves. In addition, in recent years, we have focused considerable attention on the elimination of coverage for outmoded or inappropriate health care technologies.

Our form of assessment begins when a member Plan receives a claim for a procedure that is not already recognized as either generally accepted medical practice or experimental/investigative. The Plan then either makes its own determination, using locally available advisory resources, or asks this Association to evaluate the new procedure. In these cases, the determination needs to be made quickly because an outstanding claim requires a decision.

Frequently, sufficient objective information is available on which to base a response. Where a more judgmental response is required, the data and available studies are presented to our national medical advisors. These advisors analyze the data and evidence and make recommendations back to the Blue Cross and Blue Shield Plans. The recommendations are then weighed by each Plan against the unique circumstances in its area.

In the typical assessment, the approach is to analyze the information to determine whether, and under what conditions, the new procedure results in predictable and desirable outcomes. The analysis may show that the procedure can be used successfully when the diagnosis is "x" but not "y." Thus, the procedure may be considered generally accepted medical practice, but only under specified circumstances.

To support the process of technology assessment, the Blue Cross and Blue Shield Association has built an information network with a number of medical organizations. Among these, the American College of Physicians and more recently the American Medical Association have established technology assessment programs of their own that respond to inquiries from interested parties.

We also maintain close communication with governmental agencies with interests in such activity. The Congressional Office of Technology Assessment, the National Center for Health Services Research, the Center for Disease Control and the Food and Drug Administration provide information and analysis. Staff from the Health Care Financing Administration and OCHAMPUS frequently attend our meetings and participate in our discussions. The objective, obviously, is to share information and maintain consistency, or at least an understanding of any divergence between major payment programs.

I would like to briefly describe another approach to assessing medical technologies, the Blue Cross and Blue Shield Association's Medical Necessity Program. This program grew in large measure from the information network I mentioned earlier. Since its inception in 1977, it has relied on scientific and medical technology guidance from over 20 nationally prominent professional medical organizations and societies such as the American College of Physicians, American College of Radiology, American College of Surgeons, American Academy of Pediatrics and the College of American Pathologists, to name just a few. In the early years of the program, the focus was on outmoded technologies. In recent years its focus has been on useful but inappropriately utilized medical technologies. Currently, the Medical Necessity Program includes three components: the Procedures List, Hospital Admission Test Batteries Policy and Ancillary Care Guidelines.

The Procedures List, the original component of the program, addresses medical and surgical technology procedures which are considered to be outmoded or of dubious usefulness. Since the Procedures List was released and implemented, with 42 procedures in 1977, it has been expanded to 85 procedures. Most Plans will not pay for these procedures without specific justification. But equally important, they will pay if clinical circumstances support their use. Thus, responsive administration is critical in the success of the program. There has been a dramatic decline in the utilization of these procedures.

The second component of the Medical Necessity Program addresses the unnecessary use of routine hospital admission tests such as blood hemoglobin, urine analysis, bio-chemical blood screens, chest x-rays and electrocardiograms. Plans ordinarily pay for these tests only when a physician specifically requires them. Following the release and implementation of this policy in 1979, there has been a steady decline in the use of routine hospital admission tests.

The third component and current focus of the Medical Necessity Program is on the inappropriate utilization of inpatient ancillary care technologies. The Respiratory Care

Guidelines were the first in this guideline series. Preliminary indications are that the Respiratory Care Guidelines, which were developed in conjunction with the American College of Physicians, American College of Surgeons, American College of Chest Physicians, American Society of Anesthesiology, American Academy of Pediatrics, National Association of Medical Directors of Respiratory Care and the Academy of Family Practice, have contributed to a decrease in the inappropriate utilization of respiratory care technologies in an inpatient setting. Shortly we will release Diagnostic Imaging Guidelines and we expect a similar decrease in the inappropriate utilization of these technologies. Currently, we are working on guidelines for Cardiac Care and Laboratory and Pathology Services, both of which will be released within the next year.

We are gratified by an increasing interest in these guidelines by hospital management as a means by which expenditures can be reduced under prospective payment, while maintaining the quality of care at professionally determined levels.

I must point out, however, that while we have enjoyed the advice and cooperation of the various medical groups, when we reach a decision point with respect to coverage, that decision is strictly a determination of the Blue Cross and Blue Shield Association and its member Plans.

We are proud of the accomplishments of the Medical Necessity Program and, Mr. Chairman, we appreciate your acknowledgement of the program's success in your introductory comments on S. 2504 last March.

A National Capacity for Technology Assessment

In addition to the capacities of individual third party payers, and the provider and manufacturing communities, there is a critical need for a national entity to provide a continuing, thorough, longer range review of technology issues. Importantly, S. 2504 recognizes this need and makes some provision for federal assistance in meeting it. We believe, however, that federal assistance in the form of a grant would be more appropriate than a line of credit. The Institute for Health Care Technology Assessment should be a national entity with permanent financial support coming from both public and private sources. The recent Institute of Medicine proposal to establish "A Consortium for Assessing Medical Technology" offers a useful vehicle on which to build such an entity and is not inconsistent with the approach embodied in your legislation. We believe that the funding recommendations in that proposal — a three year build-up, to $1 million annual level for core operations, with half the support coming from the government and half from private sources — is reasonable. We are willing to contribute our share to such an enterprise - and urge you to consider including a grant authority to allow the federal government to contribute its share.

The information and evaluations that should flow from such an organization would serve many purposes, including raising the level of intelligence on which third-party payers make their coverage decisions, and, perhaps more importantly, supporting the best possible clinical applications of the technology. The functions of the entity should be to detect, follow, and support analyses of new technologies long before they become coverage issues. The central characteristics of such an entity must be competence and credibility. The entity must involve and include able representatives from many disciplines under non-partisan, independent auspices.

Had such an organization been in place ten years ago, it could have and should have accumulated and evaluated the earliest information on organ transplants, identified prospectively what data should be captured to permit ongoing and consistent evaluation, and perhaps have established a research agenda to acquire additional critical information. Clearly, other technologies which are in their embryonic stages today will be confronting us in a few years with problems of comparable importance. The need is less for an entity whose interests are focused upon a single technology than for one which is more versatile and which, on a continuing basis, can deal with the broad range of clinical development. Further, reports by such an organization, supported by both the public and the private sectors, would have a broader base of acceptance than similar reports issued by third party payors, by the government alone, or by private organizations.

We believe that the need for such an entity is both clear and urgent and merits the support of the government and the private sector.

Summary

Mr. Chairman, in summary, we believe that every third-party payer should have the capacity to determine what medical technologies it will pay for and under what conditions and circumstances. We support funding for such a capacity within the government for its financing programs so long as decisions flowing from the organization or agency performing that function are not to be construed necessarily as precedents for the private sector. We also strongly support the creation of a national entity to perform a continuing and longer range review of medical technology questions and issues along the lines proposed by the Institute of Medicine. This should be a public-private partnership with a fixed financial contribution coming from the government and the private sector.

ANSWERS TO QUESTIONS FROM SENATOR GRASSLEY

1. It appears from testimony of several witnesses, yourself included, that there is quite a bit of new effort in this technology assessment area as a consequence of heightened consciousness of the relationship between technological changes and health care cost. Are we going to see still more of this, and, if so, do we need a federal effort, or a federally inspired effort, directed toward the private sector?

   o We do not believe we need a new federal effort. What is needed is joint public-private coordination. The implications of a federally inspired effort directed toward the private sector are not wholly clear to us. We reiterate our position that federal efforts should not unduly influence private efforts, although they should support private decisionmaking.

2. You take the position in your statement that the federal government should strengthen its own capacity in health care technology assessment related to Medicare and other federally financed health care programs. Dr. Brandt, I think it's fair to say on the basis of his statement, argues that whatever additional capacity the federal government needs can be met by the results of private sector efforts. Would you agree with this, and if not, why not?

   o We took the position that we would support strengthening the federal government's capacity. This could mean additional resources, or it could mean re-orientation of existing resources, as is being done with the Technology Coordinating Committee under NCHSR. The extent and degree of strengthening federal capacity is basically an administration decision. We infer from Dr. Brandt's statement a need for synergism between federal and private efforts, which we support. We think the umbrella organization that we recommended would move in this direction.

3. Both you and Dr. Brandt mentioned the Institute of Medicine's plan. You mentioned that their plan is not inconsistent with S. 2504. However, Dr. Brandt seemed to support the IOM plan, but have reservations about this bill. From your point of view, what are they key differences between the IOM plan and the program the bill would establish?

   o The key differences between the IOM plan and the bill are governance and line of credit v. direct financial support. It is our understanding, however, that these provisions have been recently amended by Senator Quayle. In the amended version, the National Academy of Sciences (NAS) would receive a $2 million grant for the development of a health care technology council. Of this amount, $500,000 would be to establish the council and the remaining $1.5 million would have to be matched by private sector funding. We support this amendment.

ANSWERS TO QUESTIONS FROM SENATOR KENNEDY

1. We are particularly interested in learning whether your organization conducts systematic empirical research such as clinical trials on the efficacy and effectiveness of medical technology and procedures.

   o We do not conduct clinical trials, although Plans typically pay the hospitalization costs related to clinical trials, even though they might not pay for the procedures under investigation. We have had conversations both with Dr. Perry's old center and with a private sector coalition about financing clinical trials. We are open-minded about expanding our role in this area. However, there are some significant problems to be overcome, including administrative feasibility, given 300 million claims per year for processing; consensus building among payors to support such expenditures; the anti-trust implications of voluntary organizations allocating a market to specific researchers; the authority under subscriber contracts to pay only selectively for procedures; the need to develop a critical mass of payors/Medicare carriers in order to prevent the technology from end-running the clinical trial; equitable spreading of the costs between classes of payors; and the development of a reciprocal commitment by the medical profession to withhold billing for unproven technology pending the outcome of the trial.

2. How do you establish priorities in determining topics for investigation?

   o While we do not conduct original empirical investigations on medical technology, we do perform secondary analyses of the medical technology literature in conjunction with our medical consultants and the professional specialty societies. The issues that we analyze are recommended by our member Plans. Contractual payment concerns typically underly these recommendations.

Senator QUAYLE. This has a lot of power, doesn't it?

Thank you very much, Mr. Morris.

I might tell all the witnesses that your entire statements will be inserted in the record.

Next is a very special witness for me, who has been a long time and dear friend from my second hometown, I guess you might say, Huntington, IN, being my first. From Fort Wayne, IN, it is a pleasure to have you before the committee. He has given me a lot of advice privately and I can't wait to see what he is going to say publicly. Mr. Rolland.

STATEMENT OF IAN ROLLAND, CHIEF EXECUTIVE OFFICER, LINCOLN NATIONAL LIFE INSURANCE CO., FORT WAYNE, IND., REPRESENTING THE HEALTH INSURANCE ASSOCIATION OF AMERICA

Mr. ROLLAND. Thank you, Senator.

My name is Ian Rolland. I am president and chief executive officer of the Lincoln National Life Insurance Co., Fort Wayne, IN. I am also appearing on behalf of the Health Insurance Association of America. I appreciate this opportunity to comment on S. 2504, which we believe addresses in a constructive way the serious problems involved with health-care-technology assessment.

The introduction of new medical technology is one of the major factors in rising health-care costs. We are, of course, concerned that the traditionally high quality of care in the United States be maintained. At the same time, however, with health-insurance premiums rising at about twice the rate of inflation, we are concerned that an organized and effective effort be made to evaluate technology, both old and new, to determine its cost effectiveness.

Our corporate health-insurance clients, who are paying a large part of the total bill for health care, demand that this be done. As I understand S. 2504, it would seek to create a means to order priorities and to coordinate information developed by all who are engaged in assessing medical technology. Your Institute would give the private sector a position of potential leadership in this area.

At Lincoln National we adjudicate medical claims involving use of new drugs and technologies on the basis of their approval by the Food and Drug Administration and, to a lesser extent, other public and private entities. This is useful as far as it goes. The FDA and others are concerned with safety and efficacy. We are not, however, able to base our coverage on sound criteria involving long-range cost effectiveness. We are further hampered by the lack of coordination existing among the many public and private organizations which are involved in health care technology assessment. We believe S. 2504 is an important part of the needed revamping of the assessment process.

It would appear that you have modeled your Institute for Health Care Technology Assessment after the Medical Technology Assessment Consortium designed and recommended recently by the Institute of Medicine. The HIAA was involved in this laudable effort by the IOM and endorsed in principle the establishment of a consortium. Further, the HIAA recommended that its member companies give high priority to this area in budget and contributions.

I support your initiative as a constructive part of a larger effort to bring greater cost and quality discipline to the field of medical technology assessment. Let me nevertheless comment on two of its aspects which we think could be strengthened.

First, S. 2504 calls for a line of credit for $2 million for 7 years to be provided by the Federal Government to the Institute. The participants in the IOM project broadly supported the idea of a 50-50 partnership between the public and private sectors. We would ask that you consider amending your financing provision to take account of this important concept. We fear, first, that Federal support could ~~dry up~~ before your Institute has been able to mature and become effective; and, second, that therefore it would become wholly private in nature and suffer a lack of credibility thereby.

Second, we prefer that the makeup and selection of the governing board of your Institute be handled as recommended by the IOM. For example, the board could be appointed by the president of the National Academy of Sciences on recommendation of the president of the Institute of Medicine, following appropriate consultation. Board members should represent an array of expertise—that is, financing of health care, provision of health care, management of health care institutions, and research, development, and marketing of health care technologies, from both the public and private sectors. It should not be representative of specific organizational entities.

In summary, the HIAA supports the proposed legislation to facilitate the establishment of the Institute of Health Care Technology Assessment for two major reasons: One, we see the Institute as being a vehicle for the implementation of the Institute of Medicine's Technology Assessment Consortium, an entity that has the strong support of the HIAA. Two, your Institute could compliment a vitally needed enhancement of Federal activities in the area of medical technology assessment embodied in H.R. 5496 and in Senator Kennedy's bill, S. 2452, bills that also have the support of the HIAA. In fact, we would like to encourage you to work with Senator Kennedy to achieve a compromise similar to the one reached by Congressmen Madigan and Waxman.

The HIAA recommends that your legislation be amended to strengthen the Federal role in support of your Institute, so that the need for private/public partnership on a 50-50 financial share of support basis can be put into place to ensure its long-term viability. We also recommend that the governing board provisions reflect recommendations of the IOM.

We hope this presentation will help in your consideration of this matter, and look forward to answering questions.

Senator QUAYLE. Thank you very much, Mr. Rolland.

Dr. Leaf?

STATEMENT OF ALEXANDER LEAF, M.D., CHAIRMAN, DEPARTMENT OF PREVENTIVE MEDICINE, HARVARD MEDICAL SCHOOL, BOSTON, MA.

Dr. LEAF. My name is Alexander Leaf. I am a medical doctor and a certified specialist in internal medicine. I currently am professor of medicine and Ridley Watts professor of preventive medicine at Harvard Medical School, and chairman of the department of preventive medicine and clinical epidemiology there. Before assuming these positions in 1981, I was for the preceeding 15 years the Jackson professor of clinical medicine at Harvard and chief of medical services at the Massachusetts General Hospital. I have served in a professional relationship to that hospital for the past 40 years. I am member of the IOM and a member of our National Academy of Sciences. It is a pleasure to express my views to your committee.

Since I have submitted a written statement, I am going to excerpt just a few points from that for the sake of time.

I think we all appreciate that there is an increasing implementation of new technologies into the practice of medicine. Some of these will be expensive, some inexpensive, some safe, some not so safe, some efficacious and not so efficacious. The question is, how do we determine which new technology or old technology falls into the repsective category? When I talk about technology, I am not talking about just the high technology of NMR imaging or CAT scanning. I think we are talking about all the procedures physicians use, diagnostic tests, the drugs, the special facilities that are used and the decisions that are made about using these technologies.

Once a new technology is reported, physicians—who are always seeking means to expand their diagnostic and therapeutic armamentarium, are quick to apply it. It is estimated that of the technologies which physicians use today, perhaps only 10 to 20 percent have undergone the kind of rigorous evaluation to determine the efficacy, the safety, and the cost of those decisions. Since third party carriers generally pay for what is acceptable and customary practice in the community, the physician gets remunerated for the introduction of these innovations. There are no incentives first to establish the efficacy, the cost, or the safety of most of the procedures and technologies which are introduced into practice.

Today, when the number of diagnostic and therapeutic procedures are legion and ever-increasing, I think we can no longer afford to take a laissez-faire attitude toward what is being done. I say this not because physicians are frivolous in their use of technology. Almost all physicians are very concerned about doing the best possible thing for their patients. However, when there is no clear evidence from careful evaluation which of the many possible diagnostic or therapeutic modalities is best for the patient, you have to make ad hoc decisions as best you can, and these decisions determine often the utilization of expensive, redundant, or even harmful technologies. Unfortunately, much of practice today must be based on such inadequately informed decisions because the data needed is simply unavailable.

We do have, on the other hand, today the encouraging point, well-developed techniques for randomized clinical trials and other control tests utilizing statistical methods to demonstrate the efficacy, safety, and cost of new procedures, and these I should think we would apply to new technologies and in time to currently used technologies before allowing these procedures and technologies to be introduced widely into practice. Therefore, I think what we need is some national facility with Government support to encourage and support research in technology assessment and to aid in disseminating the results of such studies, making them available to the medical profession, the public, and third parties. Physicians will change their behavior when the knowledge is available, and the third party payers can notify the medical profession and the public that they will no longer remunerate for technologies which careful testing has shown not to be effective, not safe, or redundant.

Now I say this because I don't sense that a consortium of private enterprises is going to do the job. The private sector is in this to make profit, and it seems that only if the consumer, the public, through a Government agency is most strongly represented in evaluating the technology, will there be significant reductions in the misuse of the technology we have today. I would think that some beefing up of the capability of the National Center for Health Services Research might provide that outlet.

[The prepared statement of Dr. Leaf follows:]

6/5/84

Testimony Presented to the Senate Committee on Labor and Human Resources
by
Alexander Leaf, M.D.
Professor of Medicine and Ridley Watts Professor of Preventive Medicine
and
Chairman, Department of Preventive Medicine and Clinical Epidemiology,
Harvard Medical School
Physician, Massachusetts General Hospital
June 7, 1984

Today an ever increasing number of new technologies - procedures, diagnostic and therapeutic measures - are being introduced into the practice of medicine. Some will be effective and even inexpensive, some will be effective but very expensive, others may be ineffective but expensive, and a few may be both ineffective and inexpensive. How will the medical profession and the public know into which category a new technology will fall? There is no problem recognizing which are expensive, but which accomplish the goals claimed for them is often not readily evident.

The Food and Drug Administration regulates drug usage so that new medicines are carefully evaluated for safety and effectiveness before they are released for general use by the public, and then often only by physicians' prescription for specific indications. We have no comparable requirements before a new surgical procedure or diagnostic procedure is introduced. Once a new technology is reported, physicians, always seeking means to expand their diagnostic and therapeutic armamentarium, are quick to apply it. Since the third party reimbursement system will pay for whatever is accepted and customary practice in a community, the physician is generally rewarded fiscally for such innovations. There are no incentives first to prove effectiveness or need for use of the technology. Thus in time physicians may be performing excessive numbers of coronary angiograms, endoscopic examinations, coronary artery bypass graft operations, cholecystectomies, tonsillectomies, etc. A surgical procedure or diagnostic procedure gradually has the indications for its use expanded over time by well meaning physicians. The history of Medicine is replete with diagnostic and therapeutic modalities which flourish even for decades, supported by devoted adherents, only finally to be shown to lack effectiveness or even to be harmful - such as blood letting and use of purgatives which survived until a generation ago. A few decades ago there were few things physicians could do to and for their patients. Today, when the number of diagnostic and therapeutic procedures are legion and ever increasing, we can no longer afford a laissez-faire approach to the problem - the risks and costs of continuing to ignore the problem are too great.

Let us consider the situation for a moment from the point of view of the third party payer. When a new technology that increases medical costs is introduced into practice the insurance companies that pay for the additional costs simply pass those costs on to the consumer through higher insurance premiums. Since the increases, divided over many subscribers, have been relatively small, the subscribers until recently have not objected to the premiums and there has been no incentive for the insurers to examine the products which they are buying. That the employer pays much of the health insurance costs has further buffered the rising costs from the consciousness of the subscriber. But the high cost of many new medical technologies and their impact on national health costs make it imperative that we scrutinize carefully what we are purchasing both for effectiveness and for cost. None of us manage our personal finances by accepting whatever the salespersons recommend.

There are now well developed techniques for randomized clinical trials and other controlled tests utilizing statistical methods to demonstrate the efficacy, safety and costs of a procedure. These statistical methods can reduce the probability that a seemingly beneficial effect is simply due to chance. We should insist that new technologies are subjected to such rigorous evaluation before being released for general use. Remuneration for use of these technologies should not be provided until evidence of acceptable assessment is forthcoming. This means that when a new dignostic procedure, like computer aided tomography or nuclear magnetic resonance tomography, is proposed for general use the indications for its use, its diagnostic effectiveness, what older technologies it will replace that can be phased out, its safety, its cost have all been evaluated. This means that grants be available to support the applied research necessary for such evaluation and that controls be provided to prevent purchase and dissemination of the technologies before adequate testing has been completed. There are many existing medical practices that have uncritically slipped into general use which need careful assessment, as well, but as a first measure all new technologies should be carefully examined.

We don't know what savings such scrutiny might produce. Various estimates of 20 to 40 percent of what physicians do for their patients may be ineffective, more expensive than equivalent alternatives, or even harmful. This is particularly the case for the terminally ill elderly patient. One published study* reported that 36 percent of medical admissions to a major hospital suffered from some iatrogenic illness - physician induced untoward reaction - and in 9 percent of all persons admitted the malady was life threatening. It seems that investing one percent or less of our national health expenditures to assess medical practices, with the likelihood that the saving in medical costs would be many times the costs for such testing, would be prudent business as well as medical practice.

---

* Steel K, et al. Iatrogenic illness on a general medical service at a university hospital. N Eng J Med 304:638-642, 1981.

Senator **Quayle**. Dr. Leaf, don't you agree that the private sector—in spite of their profit motive—can make a valuable contribution? They don't all come from the same perspective. If you get insurance people and hospital people and doctors in the same room and you ask them what to do about health care, I'll tell you, they won't all tell you the same thing. As a matter of fact, they'll be all over the ball park. I think that one of the problems that we had with the old Center for Technology Assessment, et cetera, was that it was just the Government, that there wasn't private participation. Therefore, I understand what you're saying, but don't you agree that there certainly is a role that can be played by the private sector as we look at technology assessment? I mean, they've got a lot of expertise out there and believe me, they don't all sing the same tune, as we are going to find out today.

Dr. **Leaf**. No; I certainly agree that one would like to have the private sector contributing very heavily to this. The only point I would make is that this has been going on now for some time and there is quite inadequate evidence of a sincere effort on the part of the private sector to make a significant control on the introduction of new technologies.

You have to remember that when NMR or CAT scans are introduced at enormous cost, that these do result in large profits. I am not against profit. I think that the assessment as to what the conditions are, how many of these we need, whether they are safe or not, is something that only the consumer is going to really be concerned about.

Senator **Quayle**. Well, I think that the term consumer has a broad definition. I mean, everybody is a consumer to some extent, and I suppose there is a difference between consumer and consumer activist, so to speak, or Government and private consumer on the other hand, but I really think that we're missing the boat, particularly with the diversified opinion that the private sector can bring. We really need them for credibility. I don't think that the problem has been the lack of attention on technology; I think that the problem has been that there hasn't been a very good process by which we have gone through and analyzed where technology has gone or where it should be going, in looking at the safety, efficacy, efficiency, et cetera, et cetera.

However, if you are going to do it only within Government, then I can hear already a lot of people in the private sector: "Well, there is another Government program, another Government bureaucrat spouting off." Really, to get legitimacy and if we are really going to get a handle on it, I think it is absolutely imperative that there be a very important, vital role for the private sector.

I would like to ask a couple of the other panelists about some of the specifics that Mr. Rolland brought up in his recommendations on perhaps changing the Senate version on 2504. He noted that the line of credit really wasn't an exceedingly meritorious idea, and suggested perhaps a 50-50 funding formula would be preferable to ensure the participation of not only the Government but also the participation of the private sector. Is this feeling shared by you, Mr. Morris?

Mr. **Morris**. Yes, Senator; it is. I said in my statement that I didn't think it was fundamental to implementing the concept; that the concept was the important part. However, it is clear that if the program is to be maximally effective it is going to have to have Federal participation and also if it is going to have an effect upon the introduction of technology, the identification and phasing out of obsolete technology, importantly the understanding on the part of the clinicians of some of the implications of the technology, positive and negative, then it is going to have to be understood by the whole range of paying, educating agencies and the whole scope of patients. Government will be a major beneficiary of this kind of activity and should be a participant in the cost.

Senator QUAYLE. Dr. Young, do you share that concern?

Dr. YOUNG. The commission has not examined the issues of organizational structure, finance, and, therefore, has no position on those specific issues.

Senator QUAYLE. What about, Mr. Morris, the point on the appointment process that Mr. Rolland raised? He said that, instead of having it by groups as such, that they could be made by the President upon the advice of the Director of the National Academy of Science. In other words, what you're saying is that rather than particular groups—although the groups would obviously have to be considered—that we ought to focus more on the expertise of individuals and trying to get that balance. Do you share that concern, about the original bill? We have done it by groups because when you get down and you start drafting a board of directors, et cetera, you have to make these judgment calls. We came down and said, "Well, the best way to make sure that we get diversification is to specify the members." That's the reason that we went with that direction, but he has said that he would prefer more of a tilt toward expertise rather than the various groups. I wondered if you shared that same concern.

Mr. MORRIS. Well, I would hope there would be some connection between the groups and the expertise. As you point out——

Senator QUAYLE. I would, too.

Mr. MORRIS [continuing]. There are various kinds of expertise that ought to be sitting at that table. It is a pretty arbitrary selection as it now stands. Perhaps it has to be. As I understand your intent, it is to get something up and going that can eventually take over its own self-governance and, as I recall the bill, it does provide absolute latitude for who may sit on that board after 5 years.

I would not particularly disagree with Mr. Rolland's point that the categories of people might be as acceptable, perhaps even more acceptable, than specifically named institutions, but I think the fundamental point is to be assured that there is clinical expertise, there is financial expertise, there is expertise in the evaluation processes themselves, and that there is—as Dr. Leaf has suggested—a point of view of the purchaser and the patient as well as the provider and the manufacturer and the payer. I think the mix as contemplated in the bill is a good mix. I think there are two or three possible alternatives to getting at that mix, and perhaps the specific is less important than the intent of getting the thing up and running with the intent of its taking over its own governance.

Senator QUAYLE. Before your testimony, I asked Dr. Brandt a question on what changes he would suggest or what bothered him about the Senate approach in S. 2504. He responded that he felt that it ought to be located in or that there ought to be more of a connection with the Health Services Research Center in HHS, rather than the way that we have it structured. My feeling is that we do need to have participation from the Federal Government, although I don't want to just have the effort get over there and become dominated by people in Government. I think that perhaps the funding formula, 50-50, is a better balance, although I don't know the amount of money that we are really talking about. However, say we could adequately finance it at 50-50 or whatever, what about this objection? Now you know where they're coming from. They have been over there at HHS and they may want to make sure that things go along in sync with what they have been doing. They want to have an input. I want them to have an input, too, but I think that in the past what has happened is that they have sort of said that yes, the private sector ought to be involved, but then there is not any real meaningful participation or sharing of information. The exchange with the private sector became more superficial than substantive. I know from an experience working on the Job Training Partnership Act, we went through essentially the same thing—trying to get people involved on that private industry council that was passed. Participation was more superficial than real. We made participation real and meaningful this time and we got a better turnout and a better product.

I wonder if you might comment, Mr. Rolland and then Mr. Morris, on Dr. Brandt's concern on the location and its connection with the ongoing Government activities?

Mr. ROLLAND. I guess we don't think that the concept in your bill is incompatible with what is going on at HHS or what is contemplated in the House bill for, as I understand it, strengthening that effort. We think the two can operate together. As we see it, the research activities in HHS would be aimed at actually doing the evaluations, looking at the procedures, the technology, and producing the information about the efficacy, the safety, and the cost effectiveness of these procedures. Therefore, we would support that idea and support the strengthening of that effort. We see the institute envisioned in this bill as being one of disseminating information, acting as clearinghouse, providing information to the parties that will use it, private payers, to medicare. We also see your institute as maybe providing information on which procedures ought to be evaluated, particularly what are the interests of the users of this information in having certain evaluations done, so we can see a cooperative relationship between these two efforts. We don't see them as being in conflict at all. I think they could exist side by side.

Senator QUAYLE. Mr. Morris?

Mr. MORRIS. I agree with what Mr. Rolland just said. It seems to me that it is important for an entity of this kind to have independence. The coordinating council is not and I suppose should not be wholly independent, but the functions as spelled out in S. 2504 are somewhat different from the functions as I understand them of the coordinating committee. You have put emphasis upon training in assessment. You have put emphasis upon criteria for assessment, what constitutes a good assessment process. You have put considerable emphasis upon secondary assessment as against primary assessment, synthesis, and I think that these are things which require not only an independent point of view but perhaps a full-time, dedicated staff, which I am not sure the coordinating council has. I don't see them in conflict. I see them as complementary, and I don't think the existence of one deprecates the need for the other.

Senator **Quayle**. Let me just ask two other quick questions: One, it has been said by some that we really have enough technology assessment out there right now. I think I have heard the statistic that there are 40-some entities that are doing technology assessment, and this is just going to be another institute or another vehicle to do technology assessment and it is really not needed. Would you care to comment on that? That is one of the criticisms I have heard of this bill. Mr. Rolland first, and then Mr. Morris, and maybe Dr. Young, if you would comment on that, the need for a vehicle like we are trying to do to bring people together.

Mr. **Rolland**. Well, I think we very definitely see the need for this. One of our problems is in our own organization, as we try to evaluate the implications of all the technology developments that are out there—and, by the way, we do have on our staff a medical director that is very deeply involved in trying to keep abreast of all of this, and we have people in our health insurance claim operation that try to do the same thing. One of their frustrations is all the array of data that is there, all the groups that are involved in it, so they are clearly there.

I guess we have several concerns. One is that none of these groups that are involved in assessing technology focus on the cost effectiveness of the technology. They are more concerned, rightly so, with safety and efficacy. We are also very much concerned with the cost effectiveness of various procedures, and we find it very difficult to get information in that area. We also find it difficult to gather information because it is so dispersed, so we can see your institute as being very helpful to us in focusing on the issue of cost effectiveness and also bringing together and coordinating the information, putting it into a sensible form so we can assimilate it and efficiently use it in our operations.

Senator **Quayle**. Mr. Morris?

Mr. **Morris**. Senator, if the bill contemplated another entity to do technology assessment, I think I would agree with the criticism. I don't read it as contemplating that kind of entity. Doing the assessment is one of the options that the committee has, but I don't read it as being its prime purpose. I think it involves itself in some policy questions which can't be addressed unilaterally. Who, for example, bears the burden of proof in the introduction of a new technology, something that really isn't terribly well understood today. When does a technology become substitutive instead of additive? If you do this, what should you not be doing, and in what seequence should you be doing these things to get maximum cost effectiveness.

Both kinds of questions are not technology assessment in the classic sense but they are the kinds of questions that have to be asked and addressed and addressed by a variety of interests if we are going to get maximum cost effectiveness, which is one of the things that I understand this bill to be trying to achieve.

Therefore, I think it is pursuing a false premise to say that it is another entity to do technology assessment. I think it is an entity to involve itself in the management of technology assessment, with the understanding that it will continue to be done by a whole variety of organizations because it has to be done by a whole variety of organizations that can't walk away from it, but the coordinating point and the asking of some questions and the focusing of attention on some of those questions in a research agenda can be a very important contribution which, in my opinion, is not being handled as well as it ought to be today.

Senator **Quayle**. Dr. Young?

Dr. **Young**. The Commission has very broad responsibilities. The health care system is very complex. It is changing rapidly. There are significant variations in medical practice, hospital practice, and significant differences in cost, and there is more than one way to do things, yet the information necessary to examine alternative approaches, to examine the change that is occurring, to make appropriate adjustments both from a financing and a health care delivery and a quality point of view, is lacking. The commission is increasingly aware, as we start our work, of the lack of information to make the judgments, so the need for further research, further understanding in the area of technology, its application, its cost, in the area of patterns of service delivery, is great. The Commission feels that there is indeed a significant need for more information. It recognizes that there are a lot of activities currently in the private sector, and we will be looking to those and working with them. It recognizes the needs of the Federal Government, and it has to go both private and is generally supportive of moving forward and learning more about technology.

Senator **Quayle**. One final question to ask Mr. Morris and Mr. Rolland: However we structure the entity, there is going to be a financial contribution expected from the private sector. Do you see any problem with that? I mean, are we going to be able to get funding from the private sector and a commitment for a 2- to 5-year period of time? I wonder if you see any problem with that?

Mr. **Morris**. I don't know that it is without problems. We have committed to pay a fair share of the cost of establishing such an entity.

The basic question, it seems to me, is whether there can be enough promise of stable funding for a long enough period of time to recruit a good staff and assure that the confidence to execute the function will be put in place. I suspect that involves advance commitments from a number of organizations. I don't think that there ought to be a dependence upon any one piece of the private sector. It is one of the things that probably has not been explored to the extent that it has to be.

It is my own opinion that there are enough organizations that see value in this kind of approach that the funding at a reasonable level will be forthcoming, but I don't think we can proceed on the basis of first-year commitments only. We have to think in terms of a longer period of time.

Senator **Quayle**. Mr. Rolland?

Mr. **Rolland**. Well, I think it is indicative of the support this would get in the private health insurance industry that the board of the HIA has already acted to say that they view this as a priority item, that this sort of activity ought to be supported by member companies. So, I think if we can work this out so that it does provide the kind of benefits that I think it will provide to private insurance carriers that, as Mr. Morris says, it is never easy to collect contributions, but I think that the support will be there. I think very clearly and I think the leadership of the industry will promote it.

Senator QUAYLE. OK. Gentlemen, thank you very much. I have some written questions for this panel and there will be questions from Senator Kennedy.

Our next panel will be Dr. Edwin Maynard, Dr. Roy Schwarz, and Dr. Suzanne Knoebel.

We will also have a statement to put in the record.

Dr. Maynard?

STATEMENT OF DR. EDWIN P. MAYNARD, CHAIRMAN, HEALTH AND PUBLIC POLICY COMMITTEE, AMERICAN COLLEGE OF PHYSICIANS

Dr. MAYNARD. Mr. Chairman, the American College of Physicians is pleased to have this opportunity to appear before you today to outline our views on technology assessment and the roles of the public and private sectors in its performance. My name is Edwin Maynard, chairman of the college's public health and policy committee. I am an internist in active practice at the Massachusetts General Hospital and associate clinical professor of medicine at Harvard Medical School. With me today is Dr. John Ball, the associate executive vice president for health and public policy of the ACP.

The statement we present today outlines the views of the American college of Physicians on the roles of the Federal Government and the private sector in medical technology assessment and reflects the college's own long history and extensive activity in assessing the procedures and technologies used in internal medicine.

Our written statement, submitted for the record, focuses on four questions we see as central to the technology assessment debate: The role of the Federal Government, the role of the private sector, appropriate activities in technology assessment that are not now adequately carried out, and the functions of the public and private sectors.

The need for technology assessment is not at issue. The American College of Physicians, as do others, strongly supports technology assessment. There are, nevertheless, several issues related to technology assessment that are not now adequately addressed. Among those are: methodology, priorities, coordination, information dissemination, and funding.

In methodology, the state of the art of technology assessment is still young, and additional methodolgies of assessment may profitably be discovered and developed. Among priorities, assessments today are by and large being driven by the reimbursers. There is a need to examine to a greater degree the needs of the practicing physician making clinical decisions and to be more responsive to those needs. In coordination, we believe better coordination of the activity would provide less of a duplication of effort and would help the producers of assessments be more responsive to the users of assessments. Under information dissemination, it is essential that information on safety, effectiveness, and efficacy as well as valuable data on cost effectiveness and indications for appropriate utilization of the technology be disseminated broadly.

The practice of medicine is enhanced, not harmed, by valid information from whatever source.

In funding, although the priorities of technology assessment have, to a large extent, been determined by reimbursers, both public and private, those same reimbursers have been strangely loathe to pay a share of the cost of the assessment. As it stands today, many of the producers of technology assessment fund the activity. For example, the American College of Physicians, using this year, over $150,000 of membership dues for the purpose, while the users sustain the benefit.

Turning to the issues of structuring technology assessment, the Institute for Health Care Technology Assessment, as proposed by S. 2504, would be an important step in enhancing both private and public sector activities and enhancement of the dissemination of the results of assessments. However, this legislation would be strengthened or could be strengthened in two important ways.

First, the line of credit of $2 million is most probably insufficient to support the institute until it is able to become self-sustaining. We support the concept that the institute eventually be self-sustaining. However, seed funding should be sufficient so that the institute take root and grow rather than be allowed to wither.

Second, the board of directors should be revised to call for individuals within categories of expertise, not individuals who represent organizations. Such a change in the proposed legislation would enhance the probability that the institute would benefit from the best substantive advice and strengthen its chances to be a vigorous enterprise.

The American College of Physicians supports enhancing the roles of both the private and public sectors in technology assessment. Where there are gaps in those activities, the provisions of S. 2504 are likely to be quite helpful. The college supports the functions of the Institute for Health Care Technology Assessment provided by the proposed legislation.

Thank you for the opportunity to appear before you. I would be pleased to respond to any questions.

[The prepared statement of Dr. Maynard follows:]

STATEMENT
OF
THE AMERICAN COLLEGE OF PHYSICIANS
BEFORE THE
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

June 7, 1984

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

The American College of Physicians (ACP) is pleased to have this opportunity to appear before you today to outline our views on technology assessment and the roles of the public and private sectors in its performance. My name is Edwin P. Maynard, III, MD, FACP, the Chairman of the College's Health and Public Policy Committee. I am an internist in active practice at the Massachusetts General Hospital and Assistant Clinical Professor of Medicine at Harvard Medical School. With me today is John R. Ball, MD, JD, the Associate Executive Vice President for Health and Public Policy of the ACP.

The College was founded in 1915 to uphold high standards in medical education, medical practice, and medical research. Today the College represents over 60,000 doctors of internal medicine, specialists in related non-surgical fields, and physicians-in-training. Approximately one-third of our members are Fellows of the College (FACP), a designation based upon their having met standards of scholarship and contribution to the science and practice of medicine beyond their eligibility for specialty board certification in internal medicine. The ACP membership includes private practitioners providing primary health care; medical specialists in such fields as gastroenterology, endocrinology, oncology, and cardiology; medical educators; and researchers. It is the largest organization of general internists and allied subspecialists in the world.

The statement we present today outlines the views of the American College of Physicians on the roles of the federal government and the private sector in medical technology assessment and reflects the College's own long history and extensive activity in assessing the procedures and technologies used in internal medicine.

Our statement focuses on four questions we see as central to the technology assessment debate:

1. What is the role of the federal government in medical technology assessment?
2. What is the role of the private sector in medical technology assessment?
3. Are there appropriate activities in technology assessment that are not now adequately carried out?
4. How may the functions of the public and private sectors best be structured to be most productive?

Let me begin by outlining the kind of activities in technology assessment that it would seem, from a professional medical society's perspective, to constitute an appropriate federal role.

Role of the Federal Government in Technology Assessment

On a conceptual level, government has several responsibilities to the public that it serves, among which are the protection of the public purse and the assurance of the free flow of information on which people can make more informed choices. From this conceptual base, it seems valid that the federal government have a role in medical technology assessment. Functions within that role would appropriately be three: (1) determining, to the extent possible, the safety and effectiveness of the technologies for which government pays, directly and indirectly, so that the federal government -- the largest single payer for health services -- may itself be a prudent purchaser; (2) supporting the production of information, most specifically the basic science of technology assessment methodologies; and (3) disseminating information on the safety and effectiveness of medical technologies.

The issue of the federal government's role as prudent purchaser of health services, particularly of technologies, is one of which this subcommittee is well aware, but it is worth a moment to review certain historical points in the evolution of that role. From 1965, marking the enactment of Medicare, until about 1977, the federal government had no structured process for deciding what technologies, new or old, it paid for under the Medicare program. Medicare reimbursement, for the first dozen years of that program, was based on a rather pragmatic, albeit unwritten, interpretation of the law: that is, that if sufficient billings were received by the program for a technology, that technology became, in essence, "reasonable and necessary," and thus eligible for reimbursement. There was no internal process to assure that the technologies themselves were of value, and no working process to determine the appropriateness of their application.

Beginning early in 1977, and culminating later that year in the formation of the Office of Health Practice Assessment in the Office of the Assistant Secretary for Health, and in the development of written procedures for giving medical advice to the Medicare program, at that point newly in the Health Care Financing Administration (HCFA), the Public Health Service began to structure the first step of a two-step process. That process, consisting of first, a medical decision as to the value of a technology, and second, a financing decision as to its reimbursement, began to rationalize the system of reimbursement decision-making for Medicare, thus potentially starting Medicare on the difficult road to becoming a prudent purchaser.

The passage, in 1978, of legislation establishing the National Center for Health Care Technology (NCHCT) set in statute the medical advisory relationship of the Public Health Service to the Health Care Financing Administration, thus enhancing the "prudent purchaser" function. It also established two other important functions: the financial support, albeit small, of the basic science of technology assessment, and the dissemination of technology assessment information. Three years ago, at Congressional hearings on the reauthorization of the National Center, the American College of Physicians supported the Center's reauthorization on the twin bases that its functions fostered an appropriate governmental role and that its structure was appropriate to its functions.

As you know, the Center failed to gain budget support, and met its organizational demise in late 1981. Since that time, its functions have been assigned to the Office of Health Technology Assessment and to the research grant authority of the National Center for Health Services Research.

Although in a moment I will address the organizational structure of the activities in technology assessment, I would like to return to the functions that constitute an appropriate federal role. The first, evaluating technologies in order to better inform reimbursement decisions, is critical if federal health programs are to restrain their own costs. We should all agree that the reimbursement system should be concerned with paying for that which is appropriate in health care and not paying for that which is inappropriate. The most reasonable way in which decisions of this sort can be made is by utilizing information from valid technology assessment. Without such information, reimbursement decisions would be based at best on the same tenuous foundation they were based on in the first dozen years of the Medicare program: the pressure generated by provider billings. With good information, federal reimbursement programs can operate with at least minimal assurance that what is being paid for is valid medically. In addition to the information itself, the federal government needs to continue to have a defensible and open structure and process for technology assessment -- one that ensures that all legitimate interests are heard and that all relevant data are considered.

The second appropriate federal function is support for technology assessment. This function flows from a central federal responsibility having to do with information production. There are two kinds of support that the American College of Physicians views as valid: support for the "basic science" of technology assessment, and support for assessments themselves. In the first instance, the science of technology assessment is young, needing support for growth and for the development of additional and more refined mechanisms by which to evaluate medical technologies. In the second instance, present federal activity in performing assessments is limited -- limited in scope, in that it relies almost solely on the data and opinion provided without cost to the government by the private sector, such as that provided by the American College of Physicians' Clinical Efficacy Assessment Project; and limited in subject matter, in that it addresses almost solely those issues presented by Medicare reimbursement needs. Such limitations are too narrow. Further, present activity in federal funding outside technology assessment is severely constrained. As we understand it, grant support for technology assessment flows from the available extramural research funds of the National Center for Health Services Research, an institution whose extramural research budget has historically been severely limited. In a time in which the kind of information that health services research can produce is critically needed to form a rational basis for health services expenditures, it seems unwise to add another competitor -- technology assessment -- to the funding pie, without enlarging the pie.

A third federal function in technology assessment is the dissemination of information necessary for making good clinical decisions. If technology assessment information is valid enough for making reimbursement decisions, it should be sufficiently medically valid to inform clinical decision-making. More extensive efforts deserve to be made to inform clinicians of the results -- both data and recommendations -- of federal technology assessments. Such information would be most helpful in enhancing the appropriate application of technology by clinicians as it would be in enhancing the appropriateness of reimbursement decisions.

Role of the Private Sector in Technology Assessment

Technology assessment is not solely a federal role. The private sector -- clinicians, professional societies, hospitals, and technology producers -- all have roles, and all perform some of a range of functions. For example, since 1976, the American College of Physicians has participated extensively with the Blue Cross and Blue Shield Associations in the Medical Necessity Project, a project originally designed to weed out medically outmoded procedures that no longer were appropriate, either for application or for reimbursement. The Medical Necessity Project represents both the kind of cooperation and clear delineation of responsibility in the private sector that can be mirrored by the public sector. Through the project, reimbursement decisions are based on what is medically valid information. But it is the medical profession -- professional societies such as the College -- that produce the medical data and determine its validity; and the reimbursers -- the Blue Cross and Blue Shield Associations -- that decide coverage (reimbursement) policy. By analogy, parenthetically, it would seem appropriate for the Public Health Service to continue to provide the medical advice on which the Health Care Financing Administration would then make coverage decisions.

The Medical Necessity Project, in which the American College of Physicians has continued active participation, has had other effects. In 1978, it recommended policy, based on medical input, primarily from the College, that "routine" hospital admission laboratory tests not be considered routine -- that is, not applied to every hospitalized patient unless clinically valid in each individual case. Since 1978, the project has expanded its scope to the examination of the appropriate clinical indications for valuable technologies -- diagnostic imaging, cardiovascular techniques, and common laboratory tests, for example.

For the last three and one-half years, the College, through its own Clinical Efficacy Assessment Project (CEAP), utilizing a highly structured process of literature review, subspecialty society and expert opinion polling, and committee critique, has examined intensively over fifty technologies used in the practice of internal medicine. The final products of these assessments, publications two to ten printed pages in length, present the current state of knowledge of the technology's safety, efficacy, and effectiveness, and in many cases also present the clinical indications for its use, its cost, and its relative value against alternative technologies. CEAP recommendations are widely disseminated to a variety of users -- our own membership through the College's news magazine, the Observer; the membership and other physicians through the College-published Annals of Internal Medicine, with a circulation of 100,000; Blue Cross/Blue Shield; the federal government; and other reimbursers.

The central purpose of the Clinical Efficacy Assessment Project is to enhance appropriate use of technologies by the practicing internist through providing the best available information on their medical value. Working closely with Blue Cross/Blue Shield, the College has been able to help rational reimbursement decisions be based also on good medical information. Such a partnership facilitates what we believe is a basic purpose of the reimbursement system: to pay for medical procedures that are medically appropriate, and to refuse to pay for those that are not medically appropriate.

In this statement we have focused on only two of the many private sector institutions having a valid interest in medical technology assessment -- the medical professional society, carrying out a responsibility we owe to our membership and to other segments of society by assessing the medical value of what we physicians do with our patients; and the reimburser, attempting to be responsible to its beneficiaries by paying for appropriate medical procedures, and importantly, by maintaining its resources by refusing to pay for that which is without medical value. There are, of course, many others who are interested in, and perform, technology assessment: individual physicians, constantly re-evaluating the value of different technologies in their application to greatly varying individual clinical situations; researchers, performing detailed analyses of single procedures, thus providing the basic information on which clinical decisions can be made; hospitals, analyzing the cost-effectiveness of hardware to determine if its purchase will be prudent; manufacturers, evaluating both the technology and the potential market, to determine if a new technology represents significant additional benefit clinically to be marketable; and several others. Thus, there are in the private sector a host of activities being performed by a wide range of institutions, often for differing purposes. How these may appropriately interact and how they may interface with the public sector is the subject of the next two sections of this statement.

Technology Assessment Issues Not Now Adequately Addressed

There are several issues related to technology assessment that are not now adequately addressed. Among those are: methodology, priorities, coordination, information dissemination, and funding.

1. Methodology. Most present technology assessment activity relies on a combination of user opinion and research studies. Although already available data could benefit from collection and analysis, and although available techniques -- including epidemiologic studies, randomized controlled clinical trials, cost-effectiveness and cost-benefit analyses -- could benefit by more rigorous application, the state-of-the-art of technology assessment is still young, and additional methodologies of assessment may profitably be discovered and developed.

2. Priorities. Assessments today are, by and large, being driven by the reimbursers, although in some cases -- the Clinical Efficacy Assessment Project of the American College of Physicians and assessment activity in some other professional societies -- there is internal priority setting in response to membership need. Federal activity, with the valuable exception of the consensus development exercises at the National Institutes of Health, is carried out largely in response to the needs of the Medicare program. There is a need to examine to a greater degree the needs of the practicing physician in making clinical decisions and to be more responsive to those needs. After all, what technology assessment should enable is more informed, and likely more productive and more prudent, clinical decisions.

3. Coordination. Technology assessment presently is a set of separate bilateral transactions: the Health Care Financing Administration and the Public Health Service, the American College of Physicians and its membership, researchers and the scientific community, and so forth. Better coordination of the activity would provide less of a duplication of effort, and would help the producers of assessments be more responsive to the users of assessments.

4. Information Dissemination. For the most appropriate clinical decisions to be made, there are at least two prerequisites: valid information, and appropriate incentives. For the reimbursers to make coverage decisions without the dissemination of the medical bases for those decisions misses the most productive opportunity for enabling future clinical decisions to be better informed scientifically and medically. In fact, what the College has found in its working with Blue Cross/Blue Shield is that often the dissemination of credible medical information is sufficient to cause significant positive changes in practice patterns. All of the producers of technology assessments need to do a better job in disseminating the results of assessments to the ultimate users -- physicians and patients. The federal government should not shirk its responsibility as a producer of relevant information to ensure that information is widely shared. It is essential that information on safety, effectiveness, and efficacy, as well as valuable data on cost-effectiveness and indications for appropriate utilization of the technology be disseminated broadly. Although others may argue that information dissemination by the federal government represents an unwarranted intrusion into the practice of medicine, we would strongly disagree. The practice of medicine is enhanced, not harmed, by valid information, from whatever

source. To preclude the sharing of information that could potentially better inform medical decision-making borders, in our view, on the reprehensible.

5. Funding. Although the priorities for technology assessment have to a large extent been determined by reimbursers, both public and private, those same reimbursers have been strangely loath to pay a share of the cost of the assessments. That the Medicare program pays essentially nothing to determine whether what it reimburses for is worthwhile is, on its face, irrational. It would seem, on the other hand, altogether rational for the federal government, and other reimbursers, to invest some amount in order to be a prudent purchaser of health technologies. As it stands today, many of the producers of technology assessment fund the activity -- for example the American College of Physicians, using this year over $150,000 of membership dues for the purpose -- while the users sustain the benefit.

Assessing the value of new technologies would seem to be in the interest of both those who apply the technology and those who may ultimately pay for it. Yet, although physicians clearly recognize an evolution in the application of a technology -- from its use in experimental protocols, through its use in highly sophisticated settings, to its general use by the practicing physician -- reimbursers typically recognize only two stages: experimental and therefore not reimbursable; and generally applied and therefore reimbursable. What is needed is recognition of the grey zone: that significant and sometimes long period in which a technology is neither experimental nor ready for wide application, but during which when performed in certain appropriate settings the technology may clearly benefit patients. While providing some funding of the procedure under these limited applications, the reimburser could accumulate quite valuable data that would make a later reimburse/not reimburse decision better informed.

Structuring Technology Assessment

The public sector -- the federal government -- should continue technology assessment for its own purposes (to be a prudent purchaser) and for other public purposes, principally to produce information on which, in part, clinical decisions can be made. The American College of Physicians strongly supports the continuation and the strengthening of the federal government's activities in technology assessment. Specifically, the College supports the assessment of safety, efficacy, and effectiveness, and emphasizes the validity of the federal government -- principally, the Public Health Service -- performing assessments that relate to cost-effectiveness and appropriate use of technology.

The private sector -- physicians, hospitals, insurers, manufacturers, patients, and others -- should continue the host of activities in technology assessment that are necessary for appropriate clinical decision-making as well as for appropriate economic decisions. The Institute for Health Care Technology Assessment, as proposed by S. 2504, would be an important step in enhancing both coordination of private and public sector activities and dissemination of the results of assessments. The College, therefore, supports the intent of S. 2504, as well as the specific provisions having to do with the functions of the Institute. This Committee is well aware of the general support of the medical community for the proposed functions, as they reflect the consensus of an Institute of Medicine Committee that last year proposed a public-private sector consortium having many of the same functions. The American College of Physicians was privileged to have several of its Fellows sit on the IOM Committee, and a former president of the College chaired it.

The College believes, however, that the legislation could be strengthened in two important ways. First, the line of credit of $2,000,000 through the Department of Health and Human Services, available over a seven-year period, is most probably insufficient to support the Institute until it is able to become self-sustaining. It was the estimate of the IOM Committee that a minimal first year budget would be approximately $1,000,000. We support the concept that the Institute eventually be self-sustaining. However, seed funding should be sufficient so that the Institute take root and grow, rather than being allowed to wither.

Second, the Board of Directors should be revised to call for individuals within categories of expertise, not individuals who represent organizations. Such a change in the proposed legislation would enhance the probability that the Institute would benefit from the best substantive advice and strengthen its chances to be a vigorous enterprise. Although we recognize that such a change would raise the problem by whom the initial appointments to the Board would be made, we believe on balance it more appropriate that categories of expertise, rather than organizations, be named. Other mechanisms of appointment are available, as by the Secretary, Department of Health and Human Services, through the Institute of Medicine, or through a combined process in which the Congress, the Department, and the private sector participate.

Conclusion

The American College of Physicians supports enhancing the roles of both the private and public sectors in technology assessment. The federal government should continue its own activities directed toward becoming a prudent purchaser of health care goods and services and toward disseminating valuable assessment information. Likewise, the private sector must continue its own necessary activities in technology assessment. Where there are gaps in those activities, the provisions of S. 2504 are likely to be quite helpful, and the College supports the functions of the Institute for Health Care Technology Assessment provided for by the proposed legislation.

Thank you for the opportunity to appear before you today. We would be pleased to respond to any questions you may have.

Senator QUAYLE. Thank you, Dr. Maynard.
Dr. Schwarz.

STATEMENT OF M. ROY SCHWARZ, M.D., VICE PRESIDENT, MEDICAL EDUCATION AND SCIENCE POLICY, AMERICAN MEDICAL ASSOCIATION

Dr. SCHWARZ. Mr. Chairman, my name is M. Roy Schwarz, and I am the vice president for medical education and science policy for the American Medical Association. Accompanying me today is Mr. Ross Rubin, director of our department of Federal legislation. We are pleased to have this opportunity to testify before the committee and to discuss this very important area of endeavor.

Mr. Chairman, the development and use of new medical technologies have revolutionized the care and treatment of illness and injury. New diagnostic equipment provides better information with less discomforture and risk to patients. Also, new treatment procedures made available within the last two decades have provided ways for improving the quality of life and increasing life expectancy. New and improved medical technology has been a principal factor in achieving improvements in patient care.

In recent years, however, there has been a growing concern that the Nation has not paid enough attention to formal review of medical technology. A great impetus for this concern stems from the increasing cost of medical care. In order to address these concerns, numerous programs, both public and private, many of which we have heard about here today, have been initiated. The AMA has had a long history of active involvement in assessment and dissemination of new medical knowledge and the technologies derived from such knowledge. The association's weekly Journal of the American Medical Association, nine monthly specialty journals, and its wide variety of scientific programs have been central to the evaluation of new technology in medicine for many generations of physicians. In addition, our Council on Scientific Affairs has engaged in reviews and evaluations of numerous technologies and has made recommendations thereon to the practicing medical community for a number of years.

The AMA is also committed to assuring that medical education and medical practice are firmly rooted on a scientific base. In the course of advising medical educators and in designing our own continuing education activities, the association places a heavy emphasis on identifying devices and medical procedures that may be obsolete, are newly emerging, or represent controversies in the medical field.

With respect to evaluation of specific technologies in cooperation with governmental entities, the AMA and others in the medical profession have participated in numerous consensus development conferences sponsored by the National Institutes of Health and coordinated by the Office of Medical Applications of Research of the Office of the Director of NIH. The AMA's publications play a central role in disseminating the important information generated by such meetings and in heightening the cost consciousness of both practicing physicians, medical students, residents, and others involved in health-care delivery.

The AMA, in its commitment to technology assessment, inaugurated its diagnostic and therapeutic technology assessment or DATTA project in 1982. This was done in response to growing concerns about the safety, effectiveness, indications for use, and costs associated with a rapidly growing arsenal of medical technology. This program is designed to augment, not replace, the AMA's traditional technology assessment efforts. The DATTA project allows the AMA to measure the opinion and practices of physicians throughout the country concerning a particular medical technology. These opinions are routinely published in the Journal of the American Medical Association. The details of this program are contained in my full statement, and I would be pleased to discuss the DATTA operation with you in the question and answer period.

I might add that the director of that project is in the room and could give us detailed answers if that is appropriate.

A number of other medical technology assessment programs are being conducted in the private sector, as you are aware. For instance, as we have just heard, the American College of Physicians has established a clinical efficacy assessment program which evaluates the effectiveness of nonsurgical medical tests, procedures, and therapies, and makes recommendations concerning their use. Another example is the medical necessity program of Blue Cross and Blue Shield Association which evaluates diagnostic and therapeutic procedures. In addition to these, the American Hospital Association, individual hospitals and physicians, and others are engaged in such efforts.

However, a number of Government entities including the Prospective Payment Assessment Commission, the Office of Health Technology Assessment of the Department of HHS, the Centers for Disease Control, and the Office of Medical Applications of Research of the National Institutes of Health are already conducting medical technology evaluations. Leading private sector organizations, including our own, are working closely with these Government agencies.

The AMA believes that numerous technology programs currently being conducted by the Federal Government and the private sector make S. 2504 and the technology assessment provisions of S. 2452 unnecessary. With huge Federal budget deficits projected for many years, it is especially inappropriate, we think, to provide for duplication of existing activities. The AMA has further concerns about the language in S. 2452 that would require the proposed center to consider cost effectiveness and comparative effectiveness in making its assessment of the health care technology.

The AMA believes that for most new and emerging medical technologies, the assessment of their safety and efficacy must be separated from the issue of whether or not they are cost effective. This is necessary because medical technologies often do not become demonstrably, and I would emphasize demonstrably, cost effective until long after their safety and efficacy has been demonstrated.

An example of premature cost effectiveness assessment was that conducted by Federal health planners with computerized axial tomography or CT scanning. In retrospect, had the planners succeeded in greatly limiting CT scanning in its first generation form, we might not now have the improved equipment used so beneficially in patient care today. CT scanning has, as the medical literature will demonstrate, lowered costs demonstrably and has increased quality in many areas of patient care.

In conclusion, the AMA is actively involved through its DATTA project, the Council on Scientific Affairs, and its various scientific journals in the assessment and dissemination of information regarding medical technologies. In addition, we strongly support the numerous voluntary technology assessment initiatives being conducted in the private sector.

The AMA is, however, opposed to S. 2504 and the technology assessment provisions of S. 2452. The existing assessment activities currently being conducted, in our opinion, in both the private and public sectors make them unnecessary.

I will be pleased to answer any questions that you might have.

[The prepared statement of Dr. Schwarz follows:]

STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the

Committee on Labor and Human Resources

United States Senate

Presented by

M. Roy Schwarz, M.D.

RE: Medical Technology Assessment

June 7, 1984

Mr. Chairman and Members of the Committee:

My name is M. Roy Schwarz, M.D. and I am the Vice President for Medical Education and Science Policy of the American Medical Association. Accompanying me is Ross Rubin, Director of the AMA's Department of Federal Legislation. The AMA is pleased to have this opportunity to testify before the Committee concerning the AMA's efforts in the area of medical technology assessment. We will also comment on two pending proposals - S. 2504, the Institute for Health Care Technology Assessment Act, and the provisions that relate to technology assessment contained in S. 2452, the Omnibus Health Services and Health Services Research Programs Act of 1984.

Background

Mr. Chairman, the development and use of new medical technology have revolutionized the care and treatment of illness and injury. New diagnostic equipment provides better information with less discomfort and risk to patients. Also, new treatment procedures made available within the last two decades have provided ways of improving the quality of life and increasing life expectancy. New and improved medical technology has been a principal factor in achieving improvements in patient care.

In recent years, however, there has been a growing concern that the nation has not paid enough attention to formal review of medical technology. A great impetus for this concern stems from the increasing cost of medical care. In order to address these concerns, numerous programs, both public and private, have been initiated. The AMA has been and will continue to be involved in technology assessment in order to provide up to date and valid information to practitioners and patients on medical technology issues.

AMA Efforts

The AMA has a long history of active involvement in the assessment and dissemination of new medical knowledge and the technologies derived from such knowledge. The Association's weekly Journal of the American Medical Association, nine monthly specialty journals, and its wide variety of scientific programs have been central to the evaluation of new technology in medicine for many generations of physicians. In addition, the AMA's Council on Scientific Affairs has engaged in reviews and evaluations of numerous technologies and has made recommendations thereon to the practicing medical community for a number of years. These and other efforts to review new technology and provide information to physicians are a vital activity of the AMA, and they are part of an ongoing effort to provide the best analyses and information on new technology to the practicing physician and the public.

The AMA is also committed to assuring that medical education and medical practice are firmly rooted on a scientific base. In the course of advising medical educators and in designing our own continuing medical education activities, the Association places a heavy emphasis on identifying devices and medical procedures that may be obsolete, are newly emerging, or represent controversy in the medical field.

With respect to the evaluation of specific technologies in cooperation with governmental entities, the AMA and others in the medical profession have participated in numerous consensus development conferences sponsored by the National Institutes of Health (NIH) and coordinated by the Office of Medical Applications of Research in the Office of the Director of NIH. The AMA's publications play a central role in disseminating the important information generated by such meetings and in heightening the cost-consciousness of both practicing physicians, medical students, and others involved in health care delivery.

The AMA inaugurated its Diagnostic and Therapeutic Technology Assessment (DATTA) project in 1982, in response to growing concerns about the safety, effectiveness, indications for use, and costs associated with a rapidly growing arsenal of medical technologies. This program is designed to augment, not replace, the AMA's traditional technology assessment efforts. The DATTA project allows the AMA to measure the opinion and practices of physicians throughout the country concerning a particular medical technology.

The DATTA project is based in the sciences on which medicine is founded. Its expert panels of physicians are asked to address questions that are in controversy in the medical community relative to the safety, effectiveness and appropriate applications of particular drugs, devices, or medical procedures. The AMA accepts requests for an opinion on a particular medical technology from any source including third party payors. The project's objective is to provide reliable and authoritative information to interested parties as to the safe and effective applications of a particular technology in medical practice.

A reference panel of more than 600 physicians representing a broad geographic and practice spectrum of major specialties and subspecialties has been appointed by the AMA's Council on Scientific Affairs. The DATTA panel is a dynamic and growing body. Nominees are solicited from all segments of American medicine, including state medical societies, medical specialty societies, the AMA Section on Medical Schools, and other groups represented in the House of Delegates and the Councils of the Association. Panel composition is reviewed annually and additional nominees sought as specialty or geographic needs arise. Physician panelists are recruited from all areas and include physicians in active medical practice, medical education, and biomedical research.

Questions concerning a particular medical technology are sent to a group of reference panelists who are selected based on fulfillment of the following criteria: (1) representatives of major teaching centers in the appropriate specialty who are fully conversant with the state-of-the-art as it may pertain to the question raised; (2) representatives of areas of medical practice that may have occasion to use the device or procedure in their practice; and (3) representatives of primary care specialties where daily decisions are made about referring patients for the type of service in question. In each category an effort is made to reflect a nationally geographic spectrum of diverse practice environments.

DATTA panelists are required to indicate in their responses to questions whether in their experience and professional opinion the procedure or therapy under question may be classified as: established; investigational; unacceptable; or indeterminant, that is, no consensus is apparent to date. Panelists are asked to comment on the risks and benefits associated with use of the technology, to assess the value of the technology among alternative modalities available, and to identify subpopulations of patients and patient selection criteria to distinguish those individuals for whom the general rating assigned may not pertain. The last aspect of the inquiry is particularly important because it invites physicians to identify and describe subpopulations of patients for whom special considerations, or special individual cost-benefit analyses, may pertain.

Other Technology Assessment Activities

A number of other medical technology assessment programs are being conducted in the private sector. For instance, the American College of Physicians has established the Clinical Efficacy Assessment Program which evaluates the effectiveness of nonsurgical medical tests, procedures, and therapies and makes recommendations concerning their appropriate uses. Another example is the Medical Necessity Program of the Blue Cross and Blue Shield Association which evaluates diagnostic and therapeutic procedures. In addition to these activities, the American Hospital Association, individual hospitals and physicians, and many other private organizations are engaged in technology assessment efforts.

Moreover, a number of governmental entities including the Prospective Payment Assessment Commission, the Office of Health Technology Assessment of the Department of Health and Human Services (HHS), the Centers for Disease Control, and the Office for Medical Applications of Research of the National Institutes of Health are already conducting medical technology evaluations. Leading private sector organizations, including the AMA, work closely with these government agencies.

With multiple operational federal entities formally advising the Secretary of HHS on payment issues along with the large-scale activities now taking placed in the private sector, we believe it is unnecessary to establish another entity to cover the same concerns and issues. We believe that this current mix of federal and private sector activities provides a proper balance to assure that prudent decisions are made.

Proposed Legislation: S. 2504 and S. 2452

S. 2504 would authorize the establishment of a private, nonprofit Institute for Health Care Technology Assessment (Institute). The Institute would be composed of representatives of 12 national organizations together with the Secretary of HHS and the Director of the Congressional Office of Technology Assessment as ex-officio members. The purpose of the Institute would be to promote the development of "appropriate" health care technologies, the use of "approved" technologies, and the elimination of obsolete or "inappropriate" health care technologies. The Secretary of HHS would be required to make a line of credit of $2 million available to the Institute for a period of seven years.

Section 103 of S. 2452 would amend the Public Health Service Act by establishing a Center for Medical Technology Assessment (Center) in the Department of Health and Human Services. The Center would be required to make recommendations to the Secretary of HHS concerning medical technology issues and whether specific medical technologies should be reimbursable under federal health programs. In making assessments, the Center would be required to consider the safety, efficacy and effectiveness of the technology along with the "cost effectiveness and comparative effectiveness of the technology, as well as social, ethical, and economic factors." The Center would be mandated to undertake and support, by grant or contract, research concerning technology diffusion, methods to assess medical technology, and specific medical technologies.

S. 2452 would also establish a National Council on Medical Technology Assessment (Council) which would provide advice concerning the Center's medical technology assessment functions. In addition, the Council would review applications for grants and contracts the direct costs of which exceed $50,000, and make recommendations concerning whether the applications should be approved. The bill would require $4 million to be set aside for each of fiscal years 1985, 1986 and 1987 for the medical technology assessment activities provided under the bill.

AMA Concerns with the Proposed Legislation

The AMA believes that the numerous technology assessment initiatives currently being conducted by the federal government and the private sector make S. 2504 and the technology assessment provisions of S. 2452 unnecessary. With huge federal budget deficits projected for many years it is especially inappropriate to provide for duplication of existing activities.

The AMA has further concerns about language in S. 2452 that would require the proposed Center to consider "cost-effectiveness" and "comparative effectiveness" as well as "social, ethical and economic factors" in making its assessment of a health care technology. These wide-sweeping considerations could be used to channel the activities of the Center to achieve economic and budgetary targets rather than patient care goals. It is not unlikely that the threat of a financial crisis in the Medicare program could cause the Center to emphasize restraint of new technology and cost containment at the expense of desirable patient care.

The AMA believes that for most new and emerging medical technologies the assessment of their safety and efficacy must be separated from the issue of whether or not they are cost-effective. This is necessary because medical technologies often do not become demonstrably cost-effective until long after their safety and efficacy have been demonstrated. An example of premature cost-effectiveness assessment was that conducted by federal health planners with respect to Computerized Axial Tomography (CT) scanning. In retrospect, had the planners succeeded in greatly limiting CT scanning in its first generation form, we might not now have the improved equipment used so beneficially in patient care today. CT scanning has lowered costs demonstrably in many areas of patient care. Also, this technology has greatly improved patient care by eliminating the need for invasive, higher-risk diagnostic procedures in many cases.

We also question whether the Center would be capable of properly evaluating the "social, economic, and ethical" effects of health care technologies. These are judgments on which society has not itself reached agreement. For government to attempt to make such determinations and to enforce them could result in federal decisions in many sensitive areas with great impact on patient care.

Conclusion

The AMA is actively involved through its DATTA project, the Council on Scientific Affairs, and its various scientific journals in the assessment and dissemination of information regarding medical technologies. In addition, we strongly support the numerous voluntary technology assessment initiatives being conducted in the private sector.

The AMA opposes S. 2504 and the technology assessment provisions of S. 2452. The existing technology assessment activities currently being conducted in both the private and public sectors make them unnecesary.

Senator **QUAYLE**. Thank you, Dr. Schwarz.

Next we want to extend a very special welcome to Dr. Knoebel, who hails from that fine State in the Midwest, Indiana and, more particularly, the place I was born, Indianapolis, although not Methodist Hospital there.

Dr. **KNOEBEL**. You didn't also know that I was born in Fort Wayne.

Senator **QUAYLE**. Well, I was born in Indianapolis, so we traded. In any event, we are delighted to have you with us. It is good seeing you again. Please proceed at your pleasure.

STATEMENT OF SUZANNE B. KNOEBEL, M.D., CHAIRMAN, GOVERNMENT RELATIONS COMMITTEE, AMERICAN COLLEGE OF CARDIOLOGY

Dr. **KNOEBEL**. Thank you, Senator Quayle.

I am Dr. Suzanne B. Knoebel and Ellnora D. Krannert professor of medicine, Indiana University School of Medicine and chairman of the Government Relations Committee of the American College of Cardiology.

Cardiovascular disease, because of its prevalence and importance as a cause of death and disability, is a consumer of a considerable portion of the available health dollars, particularly in an aging population. Thus, the American College of Cardiology representing providers of "costly technology" in terms of dollars, and ultimately, the consumers of such technology, feels a particular obligation to contribute toward the formulation of reasonable policy for technology assessment. We appreciate the opportunity of participating in this hearing.

The American College of Cardiology believes that unless a comprehensive scientific, enduring, equitable, and flexible technology assessment methodology is widely operative the development and/or maintenance of high cost or cost raising technologies, despite their possible critical importance for individual patient management as well as for optimal utilization of our national resources, will be seriously impaired, and the quality of medicine may be irrevocably compromised.

There are several levels of technology assessment, some being presently well met and others being in the beginning phases. The first level involves the question of whether a technology is still in an investigative phase or whether it represents accepted clinical practice. Consensus on this question for most technologies can be most easily achieved. The American College of Cardiology, as well as numerous other societies, has a committee charged with responding to such queries. Decisions are based on the sensitivity and specificity of the technology and general consensus about the usefulness of the technology in clinical decisionmaking.

A second level of assessment arises when the technology has been judged to be clinically useful and to have widespread application. The question always arises, how widespread should the application be, particularly if the technology happens to be costly in the short term? In general, this second level of technology assessment also is feasible by medical societies and additional organizations to assess at similar data probably are not required. There is unanimity among medical groups on broad indications for most procedures and practices.

The third level of technology assessment is the level of present concern for it involves cost. It is perceived that medicine is filled with medical technologies, the usefulness of which is undefined, some of which are expensive and some have limited utility, but have had continuing lives nevertheless. Others provide valuable benefits for clinical decisionmaking, the formulation of management plans and at a reasonable cost.

Given limited resources, it has been proposed that now is the time that each new and eventually most older technologies should be assessed as to where they fit in the continuum from not cost effective and not beneficial to cost effective and beneficial, both for the short and long terms. To this point, no one group has had the resources or the continuing support to approach this path. Technology assessment at this level is fragmented, and, certainly, scientific technology assessment methodologies have not been influential in policy formulation. Hopefully, it is this concern that motivated S. 2504.

Formalized clinical decision analysis may provide the structure required to achieve linked medical-economic technology assessment. One appeal is that it simulates clinical practice. Each time a patient is seen, a decision must be made and the outcome of that decision is uncertain. Decision analysis reflects the strategies and the technologies that offer the greatest potential for a salutory outcome. It would be difficult to argue that a technology which most economically refines medical probability estimates for successful therapeutic outcome or diagnosis should not be supported, and vice versa. It would be difficult to argue that one that does not contribute should be supported. Physicians understand this and would accept decisions based on such analyses.

Because of the conflicting objectives of the various participants in such cost effectiveness programs, however, it is vital that the ultimate outcome values of such analyses be clear; that is, is it the quality of life, length of life, return to productivity, cost containment, or other values which are the goal? The potential for resolution of conflicting objectives may be one of the strengths of the Institute for Technology Assessment proposed in S. 2504. To properly pursue level 3 technology assessment, professional, academic, industrial and government leaders will need to find mutual areas of agreement and understanding.

In summary, technology assessment methods are needed which preserve, advance, and encourage the development of those technologies which are beneficial and cost effective and which identify marginal technologies. The bill, S. 2504, through its consortium concept, provides a beginning balanced approach, although there is some reservation concerning the proposed representation in the consortium. In addition, whether the Institute proposed can become self-sustaining remains an unknown. If it can, however, much will have been gained because a commitment will have been made by diverse groups with different goals to forward medically necessary as well as cost effective technology utilization.

I would feel that its most important charge would be to act as a catalyst for the development and evaluation of criteria and methodologies for technology assessment.

Thank you for your attention.

[The prepared statement of Dr. Knoebel follows:]

STATEMENT OF THE AMERICAN COLLEGE OF CARDIOLOGY (ACC)

ON S.2054

"THE INSTITUTE FOR HEALTH CARE TECHNOLOGY ASSESSMENT ACT"

Presented by
Suzanne B. Knoebel, M.D.
June 7, 1984

I am Dr. Suzanne B. Knoebel, Herman C. and Ellnora D. Krannert Professor of Medicine, Indiana University School of Medicine and Chairman of the Government Relations Committee and Past President of the American College of Cardiology.* Our College is made up of some 13,000 physicians and scientists.

The American College of Cardiology, representing a relatively high technology utilization subspecialty of Internal Medicine, appreciates the opportunity to participate in this hearing. Cardiovascular disease, because of its prevalence and importance as a cause of death and disability, is a consumer of a considerable portion of the available health dollars particularly in an aging population. Thus, the ACC representing providers of "costly technology," in terms of dollars, and ultimately, the consumers of such technology, feels a particular obligation to contribute its expertise toward the formulation of reasonable policy for technology assessment.

Medical technology has been defined in various ways: by the Office of Technology Assessment as the set of techniques, drugs, equipment, and procedures used by health-care professionals in delivering medical care to individuals; and, the systems within which such care is delivered; by the Committee to Plan a Private Sector Entity to Assess Technology in Medical Care at the Institute of Medicine, as a drug, device, medical or surgical procedure, or combination of the above and the knowledge necessary for their appropriate use in the delivery of patient care. The coverage is, indeed, broad. The concern of the American College of Cardiology is that the technologies utilized for cardiovascular as well as other health care, however defined, be evaluated for their medical relevance and cost-effectiveness in such a manner that policy decisions and/or regulations impacting on their utilization can be precisely and equitably assessed and applied. The ACC, as the patient's advocate, believes that unless a comprehensive, scientific, enduring, equitable and flexible technology assessment methodology is widely operative, the development and/or maintenance of high-cost or cost-raising technologies --- despite their possible critical importance for individual patient management and for optimal utilization of our national resources --- will be seriously impaired.

---

*The American College of Cardiology (ACC) is a non-profit professional medical society dedicated to ensuring optimal care for persons with or the potential for developing cardiovascular disease, and through education and socioeconomic activities, prevention of cardiovascular disease.

There are several levels of technology assessment, some being presently well met and others being in the incipient phase only. The first level, the one with which we are all most familiar, involves the question of whether a technology is still in the experimental or clinical investigative phase or whether it represents accepted clinical practice. Consensus on this question, for most technologies, can be relatively easily achieved. The American College of Cardiology, as well as numerous other societies, has a committee charged with responding to such queries. The ACC committee operates in study section format with individual committee members serving as primary and secondary reviewers, respectively. The review is based on the literature relative to the sensitivity and specificity of the technology, gathered data on the use of the technology by the cardiovascular specialist, and general consensus about the usefulness of the technology in clinical decision-making. Problems arise only when the technology is highly dependent on the skill required to appropriately administer the technology or interpret the results.

A second level of assessment arises when the technology has been judged to be clinically useful and to have widespread applicability. The question always arises --- how widespread should the application be, particularly if the technology happens to be costly in the short-term? What patients should be so treated? What patients should receive what type of preliminary evaluation? Is coronary arteriography always indicated if a patient is being considered for coronary surgery, for example, or are there variants which should be evaluated in addition to anatomy prior to making a decision about coronary artery bypass surgery, such as the presence or absence of ischemia?

In general, second level technology assessments also are feasible by medical societies and additional organizations to assess similar data and probably are not required. There is unanimity among medical groups on broad indications for most procedures and practices. The ACC has worked with the American College of Physicians and other organizations to assist Blue Cross/Blue Shield, for example, in formulating guidelines relative to the clinical indications for some of the more costly and widespread technologies. Consensus was not difficult to achieve in most cases. It is true, of course, that most physicians can rightly point out the potential detrimental effects for an individual patient of any restrictive clinical indication guidelines. Most of these arguments are retrospective, however, while medicine is probabilistic and, thus, prospective. An additional problem arises in this form of assessment when the agencies which originally requested the information attempt to further restrict and refine the guidelines. This results in adverse and destructive relationships as the physician groups have in most cases made the maximal concessions possible in the interest of relevant medicine. Further restrictions may, therefore, be detrimental to patient care and are viewed as being primarily economically motivated. Physicians cannot accept economic considerations as the sole guiding principle for health care decisions.

The third level of technology assessment is the level of present concern for it includes cost considerations. It is perceived that medicine is filled with technologies the efficacy of which is undefined. Some are expensive and have limited utility but have had continuing lives, others provide valuable benefits for clinical decision-making, the formulation of management plans and at a reasonable cost. Given limited resources, it has been proposed that now is the time that each new and eventually most older technologies should be assessed as to where they fit in the continuum from not cost-effective and not beneficial to cost-effective and beneficial both for the short and long-term. In addition, the assessment should be in such a format that the results are quantifiable and directly complementary to simultaneous clinical efficacy evaluations so that the public, physicians, hospitals, third party payers and policy makers have the information needed to make appropriate decisions relative to reimbursement whether direct or within a prospective payment package. To this point, no one group has had the resources or continuing existence to approach this task. Technology assessment at this level is fragmented and, certainly, scientific technology assessment methodologies have not been influential in policy formulation. Hopefully, it is this concern that motivated S.2504.

Formalized clinical decision analysis, with modifications as needed, may provide the structure required to achieve linked medical-economic technology assessment. The utility of any specific technologic application or management plan can be quantitatively isolated by the technique of formalized clinical decision analysis as each step in the decision making process is explicit in terms of the probability estimate enhancement, diagnostic or therapeutic, and the cost contributed by the technology. Other advantages of the process include the potential for the development of:

- guidelines for the practicing physician as well as the third party payer and the government agency concerned with providing for quality patient care, but faced with a sometimes bewildering array of diagnostic tests and therapeutic regimens. Perhaps, more importantly, the public could for the first time understand what impact technology utilization has on the level of care they receive;
- quantitative data on cost and medical efficacy to guide governmental and insurance agencies concerned with cost-containment;

- o explicit comparative data on alternative diagnostic methodologies and therapeutic modalites. It is difficult to argue against the principle that it is the technology which most economically refines medical probability estimates for a successful therapeutic outcome or diagnosis that should be supported.

Because of the conflicting objectives of the various participants in cost-effectiveness analyses, it is vital that the ultimate outcome values of such analyses be explicit, i.e., is it quality of life, length of life, return to productivity, cost-containment, shift in locus of care, or other values which are the goal? The potential for resolution of conflicting objectives and/or assessing the impact of pursuing one value on other co-existing values may be one of the strengths of the Institute for Technology Assessment proposed in S.2504. To properly pursue level three technology assessment, professional, academic, industrial and government leaders will need to find areas of agreement and understanding.

It is obvious that all clinical decison-making should not be subjected to formal clinical decision analyses. That would not be cost-effective. It is quite possible, however, that concentration on a few costly but less effective technologies might result in sufficient savings to allow meaningful advances in scientific medicine to continue. Poor or no information on technology costs and effectiveness has been expensive because of duplication, over-utilization and improperly focused demand. Methodologies which directly assess anatomic alterations of disease, which measure secondary manifestations of disease and contractile, hemodynamic or electrophysiological functioning and which assess myocardial and peripherial perfusion, metabolic state and cellular viability are vital in order that society can derive benefit from new knowledge relative to mechanisms of disease as it evolves. Ways must be found to provide for such developments.

In summary, technology assessment methods which preserve, advance and encourage the development of those technologies which are beneficial and cost-effective and which identify marginal technologies are needed. Long-term as well as short-term gains from specific technologies should be considered and the focus must not be primarily economic. S.2504, through its consortium concept, provides a beginning "balanced" approach although there is some reservation concerning the adequacy of subspecialty representation in the consortium as outlined. Whether the Institute proposed in S.2504 can become self-sustaining remains an unknown. If it can, however, much will have been gained because a commitment will have been made by diverse groups with different goals to forward medically necessary as well as cost-effective technology utilization.

The American College of Cardiology appreciates this opportunity to present its views. Thank you for your attention. I would be happy to answer any questions.

Senator **Quayle**. Thank you very much, Dr. Knoebel.

You are absolutely correct that the primary reason for our interest was an awareness that there was this fragmentation of assessment out there that what we are trying to do is to get a consolidation and a better understanding and appreciation of the whole issue, better knowledge, better data, better interpretation. I wonder, given that general outline, do you see that our approach would in effect do what we think it is going to do? How is this going to work in an operation type basis? How is this going to work?

Dr. **Knoebel**. I am not sure I am answering your question totally, but I would think it would be the understanding that would come from having to work together to develop a solid methodology that would be important. I have found, for example, that physicians don't always understand Blue Cross, and Blue Cross may not understand physicians and neither may understand other insurance agencies or the Government. If they all had to sit down together and work on the goal for assessing a particular technology understanding should result.

Senator **Quayle**. The example of the physicians and the insurance companies, when you talk about fragmentation, can you give us another example of current fragmentation right now and how it is somewhat confusing or that there is a lack of coordination?

Dr. **Knoebel**. The American College of Cardiology, for example, is approaching clinical decision analysis using the standard academic approach as promugated by the Harvard School of Public Health the technique is to determine whether a technology improves the probability for a salutary outcome of a diagnostic or a therapeutic program, so that it can be said that a technology contributes to patient outcome in terms of length of life, for example, by "*x*" percent. It is not certain that insurance carriers understand that this is why physicians look at the problem. Doctors understand that; they will accept decisions based on probabilities. They will not accept a decision that is based purely on cost. That is, if a carrier says we cannot afford a technology and, therefore we will not pay for it, that is a fragmented approach. I don't think third party payers are understanding physicians and I don't think physicians are understanding carriers. The result is unnecessary conflict.

Senator **Quayle**. Dr. Maynard, it has been suggested that the private sector initiative concerning technology assessment be housed within the Institute of Medicine, that that would be the proper environment for it to get its origins. What would be your comment on that, doing it within the IOM?

Dr. **Maynard**. I would state, from the standpoint of the American College of Physicians, which has been very active in this area for a long time that, yes, the private sector must have an ongoing and important role with projects such as our own clinical efficacy assessment project, but we see and believe that the focus of your bill is to provide proper balance between the Federal and the private sector. We believe, as others have said this morning, that the Federal Government does have an important ongoing role. Certainly, within the proposed Institute, the balance or coordination between these two groups can be most properly effected.

Senator QUAYLE. Dr. Schwarz, let's just assume for the moment that there would be a disagreement on whether this would add more duplication and perhaps more inefficiency. Let's just assume that the Congress feels and the administration agrees that there ought to be something done in the area of technology assessment. What specific concerns would you have about the Senate approach and the way we have set this out? Maybe you would like to compare that to what the House has done as far as a preference.

Dr. SCHWARZ. If I understood your question correctly, we don't have any argument about the need. The question is method, and your specific question is if this were to be implemented, what reservations might we have relative to the way in which it would be implemented.

We are not opposed to the form in which all groups who are involved in technology assessment meet to compare notes, strategize, to participate in creative thinking. We have, as I mentioned in my testimony, participated in such groups called consensus conferences at NIH many times. There is a real value in it.

However, we would be very concerned if this Institute were to become the sole and only guiding light in technology assessment. Why? Because, suppose our scientific experience, including my own personal one, is that the best outcome when you have questions about which there can be differences of opinion is that multiple groups making the same experiment, if you will, doing the same assessment, and then comparing what the outcomes are. I think that if this became a monolithic versus a multiple approach to the analysis of a given new technology you might run the risk of getting the wrong answer which would have far-reaching adverse implications.

I guess the second thing is that I would echo what we have heard before and that is that $2 million, sir, will not go very far over a 7-year period. And I guess I would go further and say I am not optimistic that the funds to make this run in the way it should run can be raised with ready ease from the sources outlined in your bill. This year alone, the AMA is putting in in excess of $2 million into technology assessment, both directly into our DATTA program and indirectly into our drug evaluation program which is a base from which our DATTA program runs. The PROPEC budget proposed for 1985 is $3.1 million. Hence, the amount of money in your bill I think is simply not adequate for the magnitude of the undertaking that you might like to carry out.

Third, I would go to a third concern and that is that if you have such a panel, you want people on that council who have expertise, who can make judgments, who have experience. I don't think that necessarily excludes that they could simultaneously be representing the organizations which you have outlined, but I think that that expertise is absolutely critical.

Those are three quick things that would concern me.

Senator QUAYLE. All right. I want to thank the panel very much. We appreciate your participation and input. We look forward to working with you. Thank you very much.

The final panel we have today is Mr. Samuel and Dr. Eddy, and we will have some questions for the previous panel from Senator Kennedy.

Welcome, Mr. Samuel. Please proceed.

STATEMENT OF FRANK E. SAMUEL, PRESIDENT, HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

Mr. SAMUEL. Thank you, Mr. Chairman. We have a statement which I assume can be put in the record for the hearing. I would like to summarize a few points quickly and emphasize a few points that we think ought to be taken into account when you are looking at technology assessment overall. The points to be emphasized relate to the extraordinary structural changes that are taking place in the health care system.

Page 2 of our statement outlines the major points that we would like to leave you with today. As it is now drafted, we think S. 2504 probably includes too much. To the extent that Congress thinks that new technology assessment activities are necessary, we think that the priorities ought to be more clearly targeted in your bill. Specifically, we feel that these authorities should be, at least in the first few years of operation, limited to serving as a clearinghouse, identifying assessment needs, and developing and evaluating assessment criteria and methodology. We think in each of those three areas, there is a substantial role which is not being played now and which could be played by some entity.

The second point is that there are fundamental changes underway in the health care system. They are drastically changing the incentives of hospitals and other providers to acquire and use technology. Frankly, this reduces the need for technology assessment as a cost-reducing mechanism. In the past, the record may well show that there has been too much utilization of technology. For the future, however, we are concerned that the danger may be that there will be too little.

The last point is one which we offer for all those who participate in discussions of technology assessment, and that is that technology assessment means many things to many people. Fundamentally, when you look at the estimates of health care savings which can be achieved—and those estimates run in the billions of dollars—the question relates to something that is not really technology. It is really patterns of medical care, utilization rates, and things of that nature, and even ethical values, which I think are pretty far removed from, if you will, a lay understanding of technology assessment. It is very important that we understand what technology is and what assessment is before we set up mechanisms.

I am going to focus now for just a few minutes on the structural changes that are in effect in the health care system, because those structural changes relate directly to the importance of cost effectiveness analysis and to the frequency with which providers and other groups are going to be doing their own technology assessments. Basically, until a year ago, the Federal programs said to health care providers, medicare providers principally, we want more, give us more. We will pay whatever it costs fundamentally; just give us more.

The signals are now drastically changed. They now say basically give us less. The chief example of this, of course, is the hospital prospective payment system with its changed incentives for the providers. The changed incentives will lead them to lower their costs per case, not incur additional costs per case.

Second, in addition to the hospital DRG system, we see an effort to avoid unnecessary hospital admissions in the first place. The DRG system has its own way of doing that through the PRO. In the private sector, we see increased cost sharing, we see capitation programs, and we see increased use of alternate types of health care. All three of these major phenomena contribute to keeping people out of the hospital, so they never go in and never have the hospital cost in the first place.

Third, we see a major societal interest in avoiding the necessity for health care at all, increased emphasis on preventive care, such things as the campaign of private citizens and the Federal Government against drunk driving, the awareness of the effects of smoking, and certain other health and wellness programs.

In short, the combination of legislation and many other forces are going to change attitudes toward utilization of medical care and utilization of technology drastically.

On pages 9 and 10 of our statement, we offer several quotes from a for-profit hospital chain, nonprofit hospital chain, and free-standing community hospital indicating that they are going to be taking a much more critical look at technology, at its application and at its utilization. If you look at the AHA's report of key trends in hospital admissions and so forth, I think you can begin to see a suggestion that this is actually occuring. For example, the most recent available quarterly report from the AHA is that admissions went from 2.7-percent growth in the quarter ending February a year ago to a 3.1-percent decline in the quarter ending February of this year.

Another factor is that admissions both for the over age 65 group and the under age 65 group are declining. Admissions in the age group over 65 for the quarter ending February went from a 0.2-percent decline in 1983 to a 4-percent decline in 1984. There is a decline as well in the admissions for persons over 65. It is unclear whether those are attributable to the winter or whether there is a longer, more structural impact.

Very significantly, I think, cost per case growth is slowing from 10.8 percent to 8.2 percent. Very significantly for our industry, and I think for considerations of technology utilization, non-labor costs per case increases (inflation adjusted) slowed from 6 percent to 1.9 percent.

All of this suggests that the intentions of the hospital system to use less technology probably will bear fruit. Consequently, technology as a cost saver does not have nearly the same importance as it did under the essentially cost plus system that we have had for some time. Consequently, our concern is with promoting new technology, not in discouraging it, and we are pleased that S. 2504 establishes that as one of its purposes.

In short, Mr. Chairman, we see the health care system in a significant period of profound change. We think that affects the utilization of technology, its acquisition, the rate at which it is utilized, and we hope that in endorsing, in perpetuating any federally inspired technology assessment effort that this will be taken into account and that those federal efforts will be narrowly and practically focused.

Thank you.

[The prepared statement of Mr. Samuel and responses to questions submitted by Senators Kennedy and Grassley follow:]

STATEMENT ON TECHNOLOGY ASSESSMENT

by

Frank E. Samuel Jr.
President
Health Industry Manufacturers Association

Mr. Chairman and Members of the Committee:

My name is Frank Samuel. I am President of the Health Industry Manufacturers Association (HIMA), a national trade association representing 320 manufacturers of medical devices and diagnostic products.

INTRODUCTION AND SUMMARY

Let me begin by describing several characteristics of our industry and its role in the economy:

- HIMA's membership accounts for more than 90 percent of domestically manufactured devices and diagnostics and makes virtually every type of device and diagnostic product on the market today. Yet most of our 320 members are small. Two-thirds have annual sales of less than $10 million.
- Developing medical products requires research investments -- investments our industry makes at a rate three times the national average. Nearly half the respondents in a survey done for the Food and Drug Administration indicated their company had introduced a significant innovation in the last 10 years.1/ Research of this kind produces health care products that, in turn, produce longer, healthier lives for patients.
- The industry's contributions extend beyond health care. Small companies create most new jobs in the economy, 2/ and this is pronounced in our industry, where the FDA survey found that one-third of the respondents had entered the market since 1976.
- Finally, our industry is one of the few in the manufacturing sector that generates a foreign trade surplus. The U.S. exports twice as many devices and diagnostic products as it imports. This highly favorable balance of trade yields 15,000 jobs directly and many more thousands indirectly.

1/ "A Survey of Medical Device Manufacturers," Louis Harris and Associates, July 1982.

2/ Between 1980 and 1982, small businesses generated the 984,000 net new jobs in the United States (the 2.6 million new jobs more than offsetting the 1.7 million slots lost by larger firms). The State of Small Business: Report of the President, 1984, p. 25. And, according to a survey by Dun & Bradstreet, small companies will acount for more than half the 3 million new employees expected to be hired in 1984.

The three points I want to leave with you today are these:

- We are skeptical of the necessity of S.2504. To the extent Congress authorizes a technology assessment institute, the institute's priorities should be targeted to complement -- not duplicate -- the current pluralistic assessment system. This could be done by limiting the institute's authorities to serving as a clearinghouse on existing information on technology, identifying assessment needs, and developing and evaluating assessment criteria and methodologies.

- Medicare prospective payment and private sector initiatives have drastically changed the incentives of hospitals, making them more cost conscious in the acquisition of technology. This reduces the need for assessment to restrain technology's costs and brings into sharp relief the necessity of limiting assessment's potential threat to innovation.

- "Technology assessment" is many different things done by many different people and groups. The federal government's assessment priority should be to help assure that its own health care purchases are made wisely. It should avoid a commitment to technology assessment that is open-ended and impractical.

I. THE PROPOSED INSTITUTE FOR HEALTH CARE TECHNOLOGY ASSESSMENT

A. We are Skeptical of the Need for Legislation

As we explain later in our testimony, some 45 groups do assessments. These assessors range from doctors, to journals, to government agencies, to professional associations. HIMA believes S.2504's creation of an Institute for Health Care Technology Assessment would simply mark the arrival of the 46th assessor and enhance the possibility of overlap and duplication among those assessors.

HIMA also believes that if there is a true need for the Institute, it could be formed by private groups (or a combination of private and public groups) without legislation. S.2504 would simply provide the Institute with a $2 million line of federal credit over seven years. It is improbable that this level of federal financial support would induce private groups to do what they couldn't otherwise do.

The 45 assessors include major insurance companies that finance millions of dollars in health care benefits annually. A $2 million line of federal credit will not be the determining factor as to whether private groups form a new assessment body. If another assessment body truly makes sense, private groups could form it now, without legislation.

B. If an Institute is Created, Its Priorities Should be Carefully Targeted

If the Committee decides an Institute is needed, the Institute's priorities should be carefully targeted. Specifically, the priorities should complement -- not duplicate -- the current pluralistic assessment system. They should try to make the current system work better and more efficiently.

As currently drafted, S.2504 would give the Institute broad authorities without direction as to priorities. HIMA believes the most useful authorities -- the ones that would do more to increase the current system's efficiency -- are contained in bill sections 2(c)(1), 2(c)(4), and 2(c)(5). These authorities should be the Institute's priorities, and we discuss them below:

o Section 2(c)(1) -- Information Clearinghouse

Making existing information available on technologies and technology assessments could be useful. Disseminating this information regularly and widely could help assessors learn of and benefit from the work of their counterparts in other organizations. (One potential partner in this activity is the National Library of Medicine, which has virtually every work on medical technology published in the world.)

- Section 2(c)(4) -- Identifying Needs

  From its clearinghouse activities, the Institute staff might identify needs in the assessment of technologies. This information, once made available to assessors, could encourage more productive research alternatives.

- Section 2(c)(5) -- Criteria and Methodologies

  Finally, a potentially productive function could be to develop and evaluate assessment criteria and methodologies. This function (which has been the subject of OTA attention) could help assessors do a better job of assessment.

  For example, many assessments purport to measure cost-effectiveness. But as the former head of OTA's Health and Life Sciences Division has noted, the techniques used have "significant weaknesses," in part, because they focus "on factors that can be quantified, such as death and financial cost, while tending to ignore nonquantitative factors, such as ethics and equity." 3/
  Refining assessment criteria and methodologies might improve the accuracy of assessments and make them a more reliable gauge for public and private decisions about technology.

By focusing on the three priorities outlined above, the Institute could avoid duplicating the work of assessors and -- at the same time -- might help make assessments more informed, relevant, and accurate.

3/ "Using Coverage Policy to Contain Medicare Cost," by H. David Banta, page 137, from Proceedings of the Conference on the Future of Medicare, House Ways and Means Committee, 1984.

II. THE RESTRUCTURED PAYMENT SYSTEM HAS REDUCED THE NEED FOR COST CONTROL TECHNOLOGY ASSESSMENTS

Much of the current attraction of technology assessment is its cost-saving potential. But that expectation ignores major changes that are occurring in health care financing.

In testimony three years ago, HIMA told Congress:

> Many of the problems allegedly linked to the development of new medical technologies -- rising health care costs, irrational utilization of services, misallocated capital equipment -- are symptoms of the current system for financing and delivering care. These problems cannot be solved by regulating or assessing technology; they require fundamental system restructuring.

The restructuring is well underway. Part of it is called Medicare prospective payment. Now beginning to be a reality for many hospitals, it seems around the corner for physicians, long-term care institutions, and other providers. 4/

The point is that technology assessment should not be directed to solving yesterday's problems. Instead, we should focus on today's problems -- such as reconciling stringent cost controls with the need for innovation and quality health care.

4/ New financial incentives are not limited to Medicare. The private sector is replete with mechanisms that have effects similar to those intended for DRGs, such as preferred provider organizations and HMOs.

A. New Incentives Mean Substantial Changes for Hospitals

Prospective payment's enactment last April meant a sea change for hospitals, locus of 40 percent of health care costs and a majority of what can be termed "medical technology," no matter what the definition.

Under the cost reimbursement system now being phased out, hospitals had no incentive not to deliver excessive services and overuse products and procedures. But prospective payment's incentives are exactly the opposite.

By paying fixed prices for specified diagnoses, prospective payment gives hospitals incentives to limit the care provided to that truly necessary to the patient. And the tendency to over-admit will be monitored and controlled by Peer Review Organizations (PROs) and, more effectively, will be discouraged by the increasingly successful efforts of payors -- especially in the private sector -- to avoid hospitalization altogether.

Inherent in these new incentives are strong biases against overuse of products and procedures and, more broadly, against products and procedures that raise costs. Development and diffusion will also be affected, since prospective payment --

> will influence hospitals' decisions to adopt new medical products or procedures and may therefore alter the rate and direction of technological change in medicine. 5/

B. Hospitals Are Responding to the New System

Prospective payment's message has not been lost on hospitals. They are moving aggressively to respond to the new incentives.

At the 87 hospitals owned by Humana Inc., "technologies will be selected which increase efficiency, decrease costs, and are safe and efficacious," according to Paulette Lankford, Ph.D., until recently the hospital chain's Director of Technology Assessment. Through its formal technology assessment program, Humana is looking for products and procedures that are more productive and less invasive and that reduce lengths of stay and labor expenses. Manufacturers "must demonstrate very clearly the cost effectiveness of their producets," Lankford has noted.

Similar steps are underway at Intermountain Health Care, Inc., a chain of 23 non-profit hospitals that has established a new department to respond to prospective payment. Intermountain's President, Scott

---

5/ "Diagnosis Related Groups (DRGs) and the Medicare Program: Implications for Medical Technology; A Technical Memorandum," Office of Technology Assessment, July 1983, p.6.

Parker, has said that prospective payment's consequences "cannot be minimized," observing:

> [H]ospitals are realizing that in the future, more equipment and higher test volumes will no longer be a successful formula ... It could be the worst thing to do, to buy that piece of equipment and increase the number of procedures.

Hospitals not associated with chains are taking similar steps to satisfy prospective payment's bottom line demands. Providence Memorial Hospital in El Paso, Texas, for example, is purchasing generic supplies. Contrasting prospective payment with cost reimbursement, Providence Vice President Tom Lawson has said that today "all purchases must be characterized by not how much revenue they will generate, as done in the past, but what it will cost the hospital." 6/

Available data suggests these kinds of actions by hospitals are having positive effects. For example, the rate of increase in the cost per inpatient case was 8.7 percent in the period November 1983 to January 1984, compared to 11.6 percent in the period November 1982 to February 1983.

We also know that manufacturers are restructuring the way they market their products. Under prospective payment, manufacturers are increasingly emphasizing cost-effectiveness -- backed up by hard data.

6/ Complementing the initiatives of the hospitals themselves is a technology series published by the American Hospital Association. Drawn from more than 70 journals, the series reports assessments on new and existing technologies.

Consider what the new incentives mean for cardiothoracic surgery. For patients with appropriate indications, hospitals now have incentives to encourage physicians to use coronary angioplasty instead of bypass procedures. In this non-surgical procedure, a physician inserts a "balloon" catheter into the patient's artery, steers the catheter to the obstructed coronary artery, then inflates the balloon, opening the blockage. On average, angioplasty costs $5,000, about a fifth of the cost of the surgery, with a shorter recuperation period and fewer work days lost.

Hospitals are not the only ones with an interest in the cost-effectiveness of products and procedures. PROs supply another layer of review, focusing in part on the one significant cost-raising incentive prospective payment gives hospitals: the incentive to increase admissions. Newly constituted and directed since prospective payment's enactment, PROs will also review procedures associated with higher admission rates -- or otherwise designated for special scrutiny.

For example, PROs will review bypass surgery, the procedure a Veterans Administration study said was overused. For many cases, the surgery will not be performed on an elective basis unless a PRO first approves the procedure as reasonable, medically necessary, and appropriate for the patient. Other high-volume procedures will be subject to PRO review before an admission or before the procedure is performed.

PROs will also try to control costs by reviewing physician practice patterns, diagnostic information for randomly selected patients, "every permanent cardiac pacemaker implantation or reimplantation procedure," 7/ and cases with extraordinaty costs or lengths of stay.

The significant point is that prospective payment is revolutionizing the way health care providers approach product unit costs and utilization rates. They are aggressively conducting their own cost-control reviews, reducing the need for such reviews elsewhere as a means of controlling Medicare costs. And, as discussed below, prospective payment is based on historical data that -- unless updated -- may not allow new technologies to be integrated into the prospective payment system.

C. Prospective Payment Highlights The Need to Limit Technology Assessment's Potential Threat to Innovation

Innovation is a remarkably fragile process that spins from the threads of new ideas the fabric of improved diagnosis and therapy. It can be easily damaged by unnecessary obstacles.

Manufacturers decide to produce a new product -- and investors decide to back new products -- only after weighing the research expenses against the prospects for market acceptance. Premature, slow, or

---

7/ Request for Proposal (RFP No. HCFA-84-015), "Operation of Utilization and Quality Control Peer Review Organization," p. 16.

otherwise inappropriate technology assessment can quickly have an impact far beyond the facts of individual cases. By adding time and costs to the research and development process (a process already extended by FDA review of products), technology assessment can compound the technical, clinical, and regulatory barriers firms already face, adding to development costs. Some important innovations, particularly those with small initial markets, won't be able to meet those added costs.

More importantly, technology assessment can have adverse effects on the psychology of innovators because it can significantly increase the uncertainty of success for a new product.

Prospective payment brings all this into sharp relief. It has so changed hospital incentives that today's problem is not one of restraining technology's costs -- the major impulse of assessment -- but of integrating new technology into the prospective payment system. That is especially important for procedures and products whose benefits are difficult for individual hospitals to afford under the historically based prospective payment methodology, but which will achieve health care system efficiency.

An example of such a procedure is implantable infusion pump treatment for cancer, cardiovascular diseases, and diabetes. Take the treatment for liver cancer. An infusion pump is implanted below the skin to deliver small, preset doses of chemotherapeutic drugs to the cancerous tissue. By targeting the liver through the hepatic artery, the pump minimizes the well-known side effects and adverse reactions, such as nausea and hair loss, commonly associated with cancer chemotherapy. This allows patients to work and lead more normal lives.

Not only that, use of the pump saves money by reducing hospital admissions. After the pump is implanted, drugs can be added to the pump on an outpatient basis and the patient need not return to the hosptial. In contrast, conventional treatment requires repeated and expensive hospital stays. One study found that the average cost per day for patients treated conventionally was $559, compared to $115 for patients treated with the pump.

Despite the new treatment's economic advantages, however, prospective payment discourages hospitals from adopting it. This is because the $3,000 price of the pump could cause the cost of care for any one hospital admission to exceed the relevant prospective payment price. Yet fewer admissions and shorter stays are exactly the benefits sought by government and private cost control measures. But, because relevant prospective payment prices cause a loss for the hospital, there is no incentive for the product to be bought.

This is a fundamental point: One of today's problems is the tendency of prospective payment not to realize the long-term savings of procedures that cost more in the short term. And today's danger is that there will be too little innovation, not too much; that there will be too little ability to improve the quality of care for Medicare beneficiaries, not too much ability.

Let me make one final observation about the infusion pump. Despite its medical advantages, it initially received an adverse Medicare coverage recommendation. Though it was ultimately recommended for Medicare coverage, the treatment was deemed experimental in the original Public Health Service evaluation -- even though it had been approved by FDA.

That is a telling example of the delays and complexities of assessing products and procedures. These factors can significantly impede innovation and delay better quality medical care for Medicare beneficiaries.

And let's not forget that bad, uninformed, or inaccurate assessments mean patients will not be treated with those improved products. Poor assessments do not yield simply conceptual results; they translate into less care or fewer treatments for the elderly.

III. "TECHNOLOGY ASSESSMENT" IS NO SINGLE THING

Underlying the comments we make above are several fundamental points about technology and technology assessment.

A. What is Technology

Technology can mean a variety of things and processes. The term has at least three definitions:

- The Product Definition: A product -- whether or not novel -- that is used in connection with a medical procedure. Some discussions define technology more narrowly to mean a novel, state-of-the-art product.

- The Procedure Definition: A medical or surgical procedure, including the products' use, but extending as well to the techniques of the health care professional in using products. Coronary artery bypass surgery, for example, could not be performed without surgical instruments. But bypass technology is not simply the instruments -- it includes use of the instruments, training, and skill that make their use creative.

- The Medical Care Definition: The totality of products, procedures, knowledge, and systems employed to diagnose and treat illness. 8/

It is important to delineate these definitional differences so that when we assess "technology" we know whether we are assessing products, procedures, or medical care.

B. What is Assessment?

The definition of "assessment" is also imprecise.

Various people and groups need and use different kinds of information on medical technologies -- insurers for coverage and reimbursement, doctors for improving their practices, and regulators for administering public programs. Assessment refers to the methods these people and groups use to gather and analyze information on technology.

- First, there are different kinds of assessments. They range from a simple search of the literature on a technology to "comprehensive policy research." 9/ At one level, assessment is compiling existing information. At another, it is analyzing the information or data through anything from rough estimates to "sophisticated

---

8/ "The Implications of Cost-Effectiveness Analysis of Medical Technology," Office of Technology Assessment, August 1980, p. 191.

9/ "Technology Assessment and Policy Making," by H. David Banta, p. 23, from Resources for Health; Technology Assessment for Policy Making, 1982.

computer-based mathematical programming." 10/ Finally, assessment can include actually collecting new data, such as through randomized clinical trials.

None of these "kinds" of assessments carry any specific meaning as to the "purpose" of the activity.

- In fact, there are many different purposes for assessments. Some assessments determine whether a procedure is part of the package of services for which Medicare will pay. This is done by the National Center for Health Services Research (NCHSR). Among the criteria used by NCHSR in such evaluations are safety and effectiveness -- the latter criterion defined to mean whether a procedure has medical value when used under actual or average conditions.

  Determining the safety and effectiveness of products is the sole purpose of FDA evaluations. But for FDA purposes, "effectiveness" means something different -- whether a product performs as intended by its manufacturers under the intended conditions of use. To clarify the analysis further, the term "efficacy" is sometimes used to mean "effectiveness" in the FDA sense.

10/ "The Implications of Cost-Effectiveness Analysis of Medical Technology," OTA, p. 18.

Some assessments are designed only to evaluate cost effectiveness. "The Cost Effectiveness of Stopping Preterm Labor with Beta-Adrenergic Treatment" is a recent example of the many technology assessments reported in the New England Journal of Medicine. In 1980, the Congressional Office of Technology Assessment (OTA) issued an entire report entitled "The Implications of Cost Effectiveness Analysis of Medical Technology" (which found that methodological and other limitations mean this form of analysis should not be relied upon too heavily).

Another brand of assessment involves determining medical appropriateness -- that is, when certain procedures should be used. These are conducted by physicians as part of the basic science of medicine and communicated through health forums, symposiums, and professional journals.

Yet other assessments have wide-ranging intentions, like NIH's assessment of the "potential legal, ethical, social, political, medical, and economic implications" of using microprocessor-based devices and diagnostics. And a relatively new type -- performed by PROs -- is aimed at assuring quality hospital care under prospective payment, as well as guarding against excessive admissions.

- Along with the variety of assessments and the variety of purposes, there is a myriad of groups, organizations, and individuals who conduct evaluations of technology.

As the former Director of the National Center for Health Care Technology testified at a Congressional hearing in March, 45 entities assess technology in one way or another. 11/

Who does it? The Equitable Insurance Company does. So do the FDA, the American Medical Association, NCHSR, Blue Cross/Blue Shield, the National Institutes of Health, the American Hospital Association, individual doctors, medical research centers, and a host of others.

In fact, much of what the multitude of medical journals publish are reports of practitioners to their peers on assessments of particular procedures. The New England Journal of Medicine, which I mentioned, is among the most prominent.

C. Federal Government Assessments

As noted above, the myriad of groups that does assessments includes the federal government. HIMA believes federal assessment resources should be

---

11/ Statement by Seymour Perry, M.D., before the House Select Committee on Aging, March 15, 1984.

targeted to a key purpose: Helping assure that the federal government makes its own health care purchases wisely.

To do that, priority should be accorded the following areas where the federal government has a direct financial stake:

- Assessments incident to Medicare coverage decisions -- HCFA decides some Medicare coverage issues on a national basis. Before making its decision on some of these issues, HCFA asks NCHSR for a recommendation on whether the technology should be covered. NCHSR assesses the safety and effectiveness of the technology incident to formulating its recommendation.

- Assessments incident to updating and recalibrating Medicare prospective payment prices and classifications -- The HHS Secretary, after considering recommendations of the Prospective Payment Assessment Commission, must periodically update and recalibrate Medicare prospective payment prices and classifications. In making adjustments, the Secretary and Commission must consider (among other things) new technologies.

- Assessments incident to other federal purchases of health care -- The federal government also purchases health care under Medicaid, Veterans Administration, CHAMPUS, and other programs.

D. Clarity In Analysis Needed

The point in all of this is to reinforce the fact that there is no single thing or process as technology assessment. Separating the various components of assessment is essential in deciding what it is we want an assessment body to do, what its qualifications and powers should be, what standards should measure its success, and what it's going to cost.

Confusion over what technology assessment is contributes to the belief by some that assessment is a panacea for cost control. In fact, powerful new financial incentives are making assessment less important as a cost containment tool.

IV. CONCLUSION: WE SHOULD DESIGN A SYSTEM THAT MEETS TODAY'S NEEDS AND TOMORROW'S CHALLENGES

As an association of manufacturers, we see a changed and changing world. We see prospective payment as a significant step in controlling costs. We see a pluralistic health care sector in which assessments are done by myriad organizations. And we see misunderstanding over the very terms at the basis of this discussion.

What we need is an evaluation process that deals with today's problems and tomorrow's challenges, not the problems of a world gone by. Let's not duplicate what already exists or try to fix a problem that is no longer there.

Today's problems include making prospective payment work better. They include assuring that quality treatments are available to patients. They include encouraging -- not discouraging -- the innovation process that promises great strides not just in quality, but in cost containment as well.

QUESTIONS FROM SENATOR KENNEDY FOR FRANK E. SAMUEL JR. PRESIDENT, HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

1. We have heard that the health industries should be primarily responsible for technology assessment and sponsorship. What assurances do we have that the obvious conflict of interest would not be reflected in reporting outcomes and recommendations?

A: We, ourselves, have not stated, and do not believe that the health product manufacturing industry should be primarily responsible for technology assessment. (As to technology sponsorship, however, if that means sponsoring the development of new technology, then we simply don't know any other way of doing it.)

In the first instance, much of the data supporting a new technology will come from academia and other research centers. It will be used to convince a government regulatory agency, usually FDA, that the new product in question is safe and effective for marketing. Thereafter, and concomitantly, another form of technology assessment will take place -- directed essentially at utilization and proper conditions, indications or subjects for use. This is an ongoing process for most technologies, involving parts of the entire health provider community and reported in the medical and health research literature, and occasionally focused on a formal technology assessment process. Almost always these formal technology assessments are conducted by government or private payors, not by product manufacturers.

Medicare prospective payment and private cost control programs significantly increase the incentives to evaluate technology critically, perhaps too critically. Public and private cost control mechanisms are making hospitals and other providers cost-conscious in the acquisition and use of technology -- precisely the end technology assessment is intended to achieve.

On pages 7-12 of our statement, we discuss the new incentives, how hospitals are responding to the incentives, and data suggesting hospital actions are having positive effects. That part of the statement also touches on the important role of PROs in evaluating technology.

2. Can you provide us with some instances when the producer of a health technology or the creator of a medical procedure has recommended that it no longer be used because of concerns about its economic cost, cost-effectiveness, efficacy or ethical reservations?

A: Medical products are removed from the market continually because of replacement by products that are more efficacious, less costly or more acceptable to patients and providers. The process typically is a joint one between developers and buyers who, through experience, decide the benefits are not worth the costs, or that new substitutes provide relatively greater efficacy or other benefits.

3. What incentives are there for manufacturers of health technology to assess the effectiveness, cost effectiveness, social impact, etc. of its products as they are applied in the system and what incentives do they have to disseminate their findings, especially when they are negative?

A: When health care providers -- especially hospitals -- are extremely cost conscious, they put pressure on suppliers, including health technology suppliers.

The same incentives that encourage providers to look for cost-effective products encourage manufacturers to develop them. As manufacturers develop products, they conduct internal reviews to ensure that the cost-effectiveness requirements of patients and providers are met. Similarly, manufacturers will conduct operational assessments of effectiveness and other criteria because -- again -- the product must satisfy the needs of patients and providers.

On page 11 of our statement, we highlight the balloon catheter and its use in coronary angioplasty -- a cost-effective procedure that can substitute for cardiothoracic surgery. And on pages 12-15, we discuss the implantable infusion pump, which is a cost-effective alternative to traditional chemotherapy treatment for liver cancer.

In the new cost-conscious environment, manufacturers increasingly will develop products like the balloon catheter and implantable infusion pump. And in the process of developing these products, manufacturers will assess on the basis of cost-effectiveness, effectiveness, and other factors important to patients and providers. And in the cost-conscious environment, the absence of positive cost-effectiveness or other important factors will be obvious and have a negative impact on product acquisition.

4. When private industry does engage in health technology assessment, does it also share the results with competing firms?

A: Manufacturing firms do not generally share results of internal assessments. To do so, would be at odds with notions of competition and innovation -- which fuel development of new products. More significant, though, is what other parts of the health care system -- providers -- do with the results of technology assessments.

As I noted above, health care providers, especially hospitals, have strong incentives to evaluate technologies and to adopt those that are cost-effective.

Certainly hospitals within a system or chain share information. Our statement, on pages 9-12, speaks to the evaluation of technology in such situations, using both a non-profit chain and a for-profit chain as illustrations.

Particularly relevant is the footnote on page 10 on the American Hospital Association's technology series. This series reports to hospitals the results of assessments of new and existing technologies.

5. If there is a sharing of research results industry-wide, what incentive is there for one company to initiate research? Why would it not choose to wait for others to make that investment?

A: Industry does not share certain kinds of research results (sharing this kind of information would blunt the incentive to innovate). Of course, the scientific literature reports on much research that underpins and relates to developmental work of this kind. However, early success with an innovation requires having information of significant benefit for the technology in case early adopters wish to use it. Typically, this information diffuses to potential competitors soon after the product experiences early market acceptance. The potential for this rapid diffusion of information on new technologies to result in competitive product development (and the attendant blunting of innovational incentives) is critical in this prospective payment environment. Preserving the incentive to innovate will demand that the prospective payment system be flexible towards accepting new developments and the DRG prices kept as current as possible. Technology assessment for Medicare coverage and consequent DRG recalibration must avoid delay so the recalibration lags are as short as possible.

6. We have heard that technology assessment can retard innovation. Is it not the case that objective, carefully implemented research assessing technology can enhance the adoption of efficacious and safe health care innovation?

A: It is possible, but unlikely.

On pages 12-15 of our statement, we make a number of observations about how assessment can affect innovation. As we point out, assessment -- even if done as well as your question assumes -- compounds the technical, clinical, and regulatory barriers firms already face.

Assessment can do two things. First, it can mean additional development costs -- costs some smaller firms may not be able to bear. Second, and more significantly, assessment can cause an adverse effect on the psychology of the innovator. This is because it adds uncertainty to a product's success.

So even if an assessment is performed as carefully as your question suggests, it can still generally pose barriers to innovation. For specific products, the right kind of assessment might indeed be helpful. These products are likely to be those which increase short-term costs, but achieve long-term costs or quality benefits.

Our final point is that it is unlikely an assessment will be performed that carefully. The statement on page 15 notes that the implantable infusion pump treatment for liver cancer was the subject of a faulty Medicare coverage assessment -- later corrected. This is an example of the delays and complexities of assessment -- factors that militate against carefully performed assessments.

7. Do you have any illustrations of how health technology assessments in the past, such as activities of the NCHCT, undermined innovation of potentially useful products or procedures?

A: I think the best example to date is noted on page 15 of our testimony relating to the implantable infusion pump. Further, the authority of the NCHCT to compile an "emerging technology list" caused a good deal of uncertainty within industry regarding its possible use as a barrier to entry.

8. Do you think that it is important for the federal government to substantially increase its commitment to health technology assessment or do you think it should be conducted exclusively by the private sector?

A: The answer lies somewhere between the alternatives stated in your question.

The private sector plays a strong role in conducting technology assessments. Private assessors include such diverse groups as the Equitable Insurance Company, American Medical Association, American Hospital Association, the American College of Physicians, medical research centers, and individual doctors.

The private sector's role should be complemented by carefully targeted federal assessments. Specifically, federal assessments should be targeted to a key purpose: Helping assure that the federal government makes its own health care purchases wisely.

To do that, priority should be accorded the following areas where the federal government has a direct financial stake:

o Assessments incident to Medicare coverage decisions -- The Health Care Financing Administration (HCFA) decides some Medicare coverage issues on a national basis. Before making its decision on some of these issues, HCFA asks the National Center for Health Services Research (NCHSR) for a recommendation on whether the technology (usually a procedure) should be covered. NCHSR assesses the safety and effectiveness of the technology incident to formulating its recommendation.

o Assessments incident to updating and recalibrating Medicare prospective payment prices and classifications -- The HHS Secretary, after considering recommendations of the Prospective Payment Assessment Commission, must periodically update and recalibrate Medicare prospective payment prices and classifications. In making adjustments, the Secretary and Commission must consider (among other things) technological advances.

o Assessments incident to other federal purchases of health care -- The federal government also purchases health care for beneficiaries of Medicaid, Veterans Administration, CHAMPUS, and other programs.

QUESTION FROM SENATOR GRASSLEY FOR FRANK E. SAMUEL JR. PRESIDENT, HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

Some witnesses stated that the federal government should be able to make sound decisions with respect to reimbursement of various health care technologies. I think you also said as much in your statement.

Would you agree with the position taken by Dr. Brandt, to the effect that any additional need in this area of the federal government can be met through use of the results of private sector assessment activities? Or would you say that the federal government's own internal capacity in the technology assessment area needs to be enhanced?

A: We think that Congress should mostly enhance the federal government's authority to determine whether it should pay for technologies under its own programs -- such as Medicare. We support strengthened capacity for the National Center for Health Services Research (NCHSR) Medicare coverage assessments so that these assessments can be done promptly and openly.

To the extent your question is directed toward assessments not performed in connection with federal programs, we do not see a federal role. On pages 4-6 of our statement, though, we point out that if there is to be expanded federal support for assessments not involved with government payment programs in this area, there are three activities that would complement the current pluralistic assessment system. Those activities are serving as an information clearinghouse, identifying assessment needs, and developing and evaluating assessment criteria and methodology.

Senator QUAYLE. Thank you.

Dr. Eddy.

STATEMENT OF DR. DAVID M. EDDY, DIRECTOR, CENTER FOR HEALTH POLICY RESEARCH AND EDUCATION, DUKE UNIVERSITY

Dr. EDDY. Thank you, Senator Quayle.

First, I should describe my biases. I am a physician trained in surgery. I also have a Ph.D in engineering, specializing in cost-effectiveness analysis and technology assessment. So, I suppose I represent those who do technology assessments and who work with organizations such as those you have just heard from, to help them design policies.

I prepared a written statement, but much of it has already been covered by previous speakers. Perhaps the most useful thing I can do at this time is to address some of the specific points that were raised in previous discussions.

First, I want to restate the importance of technology assessment. It is important we all understand the magnitude of the problem we face in medicine today. We all know that costs are rising. We all know that choices will have to be made. In order to make those choices, we must have better information or we are going to make mistakes.

As I believe Dr. Kncebel said, a technology assessment is done every time a physician thinks about the pros or cons of a particular procedure for a particular patient, or renders an opinion about how a patient should be managed. There is no question that we are doing and will continue to do technology assessments. The only question is how well.

Unfortunately, I do not think they are being done very well. There is a tremendous amount of room for improvement. Start with the fact that we have very little information about just how much a procedure can be expected to improve a person's health, the procedure's risks, its costs, and so forth.

Beyond that, analyzing the value of a procedure can be a very complicated problem. There are many different factors that relate in complicated ways, and it can be extremely difficult to sort them all out. Unfortunately physicians, who have traditionally been the ones to conduct technology assessments, are in general poorly trained for this task. They might be very well trained in surgery or some other medical specialty, but they may not be well trained in probability theory, economics, mathematics, computer science, and other sciences that are needed to assess medical technologies.

By and large we now rely on a consensus process for assessing medical procedures. However I do not believe this is nearly adequate. The consensus process is vulnerable to oversimplification, errors in reasoning, and obvious biases, such as financial and professional biases.

I do not think there is any doubt that we do not yet have an adequate system for assessing medical technologies. If you doubt this you can just ask the next physician you see about a personal health problem, to state the numbers that describe the value of a diagnostic test or treatment he or she is about to order for you. Simply ask the physician how that particular procedure will change the chance of a cure or some other outcome that is important to you. Do not be satisfied with generalizations such as "we believe the test is valuable in cases like yours;" ask for the numbers, and see what answer you get. All you will probably elicit is a severe sense of discomfort, because, in fact, most physicians don't really know these numbers—the information simply does not exist. Sit in on any NIH consensus conference and listen to the information that is being used as the basis for the decisions.

What all this means is that we are probably making some big mistakes. Those mistakes, I fear, are translated into lost lives and lost dollars. I do not believe that as a society we really appreciate the magnitude of these mistakes.

I personally believe that the loss is measured in the tens of billions of dollars and tens of thousands of lives a year. To medicare, the financial loss is on the order of $5 to $10 billion a year.

What does this mean for a Federal effort in technology assessment? First, I think it means that the effort ought to be big. The numbers I have heard are not nearly large enough. This may not be politically feasible, but I believe this area easily deserves and could support an effort on the order of $100 million a year. We spend $5 to $10 billion doing research and developing new technologies. It only makes sense to put some money into the last step in the process which determines how that research information should be translated into an actual improvement in a person's health. While the existing efforts in the private sector are laudable, I do not believe they are nearly sufficient to correct the problem.

With respect to Senate bill S. 2504, I appreciate the concerns that led to its development, but I see several problems that I think you might want to consider. First, I am not convinced that the existence of a board of directors and the existence of a line of credit, or even a grant, is the major barrier to the creation of a coordinated public-private sector enterprise. The people who are doing technology assessments can get together right now if they wanted to. There are a relatively small number of them. They all know each other. They all have telephones. They probably even meet on the golf course every now and then. They could establish a board of directors in 3 days if they put their minds to it.

I also do not think that $2 million is the stumbling block. The larger groups now doing technology assessments—largely by consenses—could come up with that much money if they chose to. The third-party payers alone pay out billions of dollars a year in claims, $2 million could be collected if the motivation existed. So my first concern is that this particular bill does not address the main barriers.

I am also concerned about the nature of the board. It should not be composed of people who have a financial or professional stake in the outcome. Representatives of the professional and corporate associations can sit on advisory committees, but the board ought to be composed of representatives of the people who live or die by how a technology is used, and people who know how technologies are assessed.

Finally, I believe the bill blurs the lines between public versus private control. The act stipulates in detail the Institute's governance and mission and even sets the honoraria of the board, but leaves it up to the Institute to do the work and to raise the money. I wonder, if the Board wanted to change the Institute's mission slightly, would it have to turn to Congress to change the act?

Finally, I believe that the effort is too small.

In summary, I think we all agree that there are important roles for both the private and public sectors, but I am not convinced that we need to think only in terms of joint public-private agency. If it is coordination we want, that could easily exist without creating a jointly funded agency. In fact, the public already sponsors many private sector activities, and people in the public sector already sit on the boards of private organizations. People in the private sector sit on advisory boards for public agencies, and in fact do much of the work, review proposals, approve concepts, and, in many cases, move in and out of private sector jobs. So, the coordination between the public and private sectors is possible without a jointly sponsored agency.

In terms of a new effort in the public sector I prefer creating a new Federal agency comparable to the National Institutes of Health, Food and Drug Administration or National Center for Health Services Research and Development. I frankly am not as discouraged about the products of the National Center for Health Care Technology [NCHCT] as others appear to be. If the main problem was that their analyses were divorced from the medical environment, then that is certainly not a problem with structure, mission or mandate of the Center; that is more a matter of direction, which could be corrected. However, if for some reason it is politically infeasible to resurrect NCHCT or create a new Center, I would advocate a major increase in funding for the National Center for Health Services Research.

I would like to close by applauding you for taking on this problem. It is a huge one, and it is extremely important. Technology assessment is the last link in a long chain that starts with a research idea and, we hope, ends up in an improvement in a person's actual health. A weakness in that last link can destroy decades of time and millions of dollars of research, and can commit us to lose millions of lives and billions of dollars in the future. I believe it deserves major support.

Thank you.

Senator **Quayle**. Thank you, Dr. Eddy.

I can assure you that at least I and others perceive this to be a major problem, but I also can assure you that with certain fiscal constraints, doing too much is just beyond the realm of political possibilities. Therefore, I wonder if we might focus on what is really possible and to look at our bill as a first step. You mentioned that the people who are involved in technology assessment have phones hooked up and they may even meet on the golf course periodically, and they could come together if they wanted to. That may be true, but I don't think they will unless there is some entity or some umbrella where they can come together in a structured way. We can offer some sort of enticement for them to sit down at the same table and for them to try to rationally discuss where we are going to go on this.

Therefore, if you accept that we have to do something rather minor, that we are not going to be able to do something major with the budget restraints we have, what do you think of the approach that we outlined in S. 2504? Would that be a good first step or not?

Dr. **Eddy**. I am still confused about the relationship between the public and private sectors with respect to the governance of the proposed Institute. The governance and mission of the Institute is stipulated by an act of Congress, yet, as I understand it, the mission is to be carried out and the money is to be raised by the private sector. I believe this split leadership, split reporting relationship, and lack of flexibility will compliance the accomplishments of the Institute's mission.

I would rather see a program that is either primarily public sector or primarily private sector, rather than a combination of the two. For the public sector, I prefer a large increase in funding for the National Center for Health Services Research or, better yet, a new independent agency. For the private sector, I would favor the straightforward approach of making a large grant to the Institute of Medicine or some other highly respected impartial body.

Senator **Quayle**. Well, the chain of command, the way that we set it out, is really dominated by the private sector. It was intended to be that way. We felt that the private sector has a great deal of the expertise and that they ought to be involved in coming together to rationalize where we are going to go. We left open the guidance mechanisms and the direction that they are going to go. We wanted to leave as much flexibility as possible.

The Government tried the Center for Technology Assessment within HHS, and it was phased out in 1981. It was just simply a Government program and it became bogged down with politics and other things and simply wasn't workable. So, this is a different type of approach. Dr. Brandt mentioned that he wished that there was more coordination, and a little bit better understanding. It seems to me that what you are saying is that perhpas we ought to put it, or at least the private sector aspect of it, in the IOM, if you are going to have the private sector initiative. Is that correct?

Dr. Eddy. Well, I was going to ask you why, since Senate bill S. 2504 was modeled after the report of the IOM, the IOM was not designated in the bill as the appropriate place for the new Institute. I will just say that the politics that the NCHCT got bogged down in were in the private sector, as indicated in the hearings that led to the demise of the center. I think that those politics still exist, and would plague a public-private sector entity, such as the Institute that is being described in the bill.

We should list the desiderata or criteria that should govern a decision about where a technology assessment unit should be. First, it must do excellent studies. Second, it must be neutral, not only politically neutral, but capable of impartial reports.

Third, I think it requires stable funding, because that affects its impartiality. The continuance of funding should be based on the quality of the products and the usefulness of the reports, not on whether the recommendations please or displease a particular group. If a new organization must rely on various organizations in the private sector for continued funding, I believe it will continue to be vulnerable to the same financial and political pressures that stopped the NCHCT. The Institute of Medicine is one of the few existing organizations in the public or private sector that might be able to withstand that pressure.

Senator Quayle. Mr. Samuel, on page 2 of your testimony, you talk about limiting the Institute's authority to serving as a clearinghouse or existing information on technology. How would that work? What, in your mind, do you mean by that?

Mr. Samuel. Let me, first of all, clarify the point, Mr. Chairman. The clearinghouse is limited to three functions that we would suggest are important for this entity. In addition to the clearinghouse function, the assessment, identifying assessment needs, and working on assessment criteria methodologies are also important. But let's go back to the clearinghouse.

We provide, on the bottom of page 4, a suggestion of how that would work. Basically, our perception is that we have a very large number of assessment activities underway now. You heard about some ~~of th~~ose. The first thing that is needed, before we start going off and doing more assessment, is that all of those entities have access to each other's work, that any of my manufacturer members would have the same, any physician, any member of the public would have access to the body of data and conclusions about technology that have come out of this whole process. We don't have that now. You can go to the National Library of Medicine and get a listing of all the reported literature works on technology and, obviously, get some of those that deal with technology assessment. However, our perception is that you can't go to one place and really have a true depository of all that is known about assessment of technology, whether it be clinical, whether it be economic, ethical, or whatever. So, that seems to us to be a function that no one else is going to do, even if they could get together on the golf course or otherwise, and I think a lot of that could take place. I must say I agree with Dr. Eddy on that point. However, even if they would do that, it would be hard for them to establish something like the National Library of Medicine or like a central depository of facts and figures that we think really must underlie all of this.

Once that is in place, and once assessors, whether the Government or the private sector, are used to pooling their research and the results of their research through this entity, and this entity disseminates and makes a practice of disseminating, through written reports, conferences, what have you, then I think you have a way of beginning to identify needs.

That is the next thing we think is important. Where are the needs for assessment? Third, how do you do it? I think Dr. Eddy's point about that is correct. I think right now we tend to undervalue qualitative benefits in technology assessment, long-term benefits, quality of life benefits. We tend to overvalue proving clinical efficacy in a clinical sense or economic efficacy. Clearly, methodological concerns are important, too.

All those are central functions. It is unlikely that any one assessor, even as big as Medicare is, if it decided this, would be able to do those central functions very well.

That got beyond the clearinghouse question that you asked, but basically the clearinghouse we see as a very essential part of the foundation of a better, more efficient technology assessment enterprise.

Senator **Quayle**. OK, gentlemen. Thank you very much.

[The following information was supplied for the record:]

acr 6900 Wisconsin Avenue Chevy Chase MD 20815 (301) 654-6900

AMERICAN COLLEGE OF RADIOLOGY

5 June 1984

Honorable Orrin Hatch
Chairman
Committee on Labor and Human Resources
U. S. Senate
428 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Seantor Hatch:

The following comments about S 2504 are offered on behalf of the 16,000 physician and scientist members of the American College of Radiology. The College appreciates the opportunity to make these comments and requests that they be made part of the record of public hearings on S 2504.

Radiologists are physicians who are trained and who specialize in the uses of ionizing radiation and other radiant energy forms for the diagnosis and treatment of diseases. The scientist members of the ACR are radiologic physicists, whose discipline underlies the development of modern radiological technology. Radiologists are directly responsible for the bulk of medical diagnostic imaging procedures and radiation treatments for cancer required by Americans at any time.

The field of radiology has been a dynamic part of modern medicine, with the advent and rapid proliferation of new technical advances being almost routine in the past two decades. From the staple x-ray procedures of 1940, we have seen the introduction of radioisotopes, of ultrasound techniques, of linear accelerators for high energy cancer treatments, of computer applications, of imaging concepts such as computed tomography, positron emission tomography, single photon emission tomography, and currently, magnetic resonance. Each of these modalities has added significantly to the ability of the radiologist to identify ranges of disease and disability. In recent years, the use of catheter techniques to restore occluded blood vessels and other body channels, to remove stones or foreign bodies and to carry medicines to specific disease sites has greatly changed medical practice, reducing patient trauma, costs and complications.

In many cases, the scientific and industrial research necessary to develop the equipment with which we undertake these procedures has been both extensive and expensive. The equipment and supporting facilities are complex and costly to obtain and to operate. Not all of our promising technologies passed our own scrutiny and survived.

All of this emphasizes that the discipline of radiology has had significant and sometimes vexing and frustrating experiences with previous public and private efforts at health planning and technology assessment. Hence, our observations about the process and our suggestions for specific approaches come from these experiences.

One of the serious dilemmas of past technology assessment efforts has been a confusion between the stated objective and the imperative of the assessor to save money in some element of health care. To be sure, cost effectiveness is one proper element of technology assessment. However, when it is allowed to become the dominant element, basic concepts and judgements about medical needs are lost.

In developing this point, we do not suggest that the Congress should detail the way in which the proposed institute should carry out its studies. But we do urge that in the bill or in report language, that it be emphasized that the purpose is to make studies for the medical practitioner and the health care facility, rather than for purposes of the host of other disciplines which have demanded that medical practice be reshaped to respond to their citeria.

A second dilemma in other technology assessment proposals has been a tendency by the assessors to ignore the entire weight and worth of the experience of the medical community with a device or modality. Clinicians do not engage in the controlled studies favored by the research community. Their testing is pragmatic and meaningful to them. Further, their judgements are made in terms of the management of patients, who present as individuals.

Again, the point is not to dictate finite detail to the institute, but to urge report language reflecting the concern of the Congress that the experience of the medical community be utilized in its assessment efforts and that the judgements be couched to have value to that community, as well as to policy makers.

This concern is somewhat occasioned in S 2504 by the proposed composition of the board of directors. Only three of 14 cited organizations directly represent physicians, whose decisions, presumably, are to be sampled, analyzed and influenced. Nurses and hospital administrators would bring health professionals up to five of 14, leaving the others concerned as suppliers or third parties. All of those groups have involvement and concerns with health care. Perhaps they will appoint physicians to represent them. But in terms of contributing to the analytical process, their contributions may be more political than scientific.

At the same time, it seems to us that the board, as outlined, would be an inefficient governing body, since its members have the potential conflict of representing their organization at the same time that they are to set policy for a functioning structure. This would be more appropriate as an advisory group, with a smaller number of physicians and investigators serving as a management committee to work directly with the staff. The larger group could be the mechanism to select the smaller management committee, with the understanding that members of the smaller group should have particular competence in medical analysis and decision making and that those individuals should not be representatives of any sponsoring organization.

These are the thoughts about S 2504 as reflecting the discussions within the American College of Radiology. If we can be of any other assistance as this receives further consideration, please call upon us through our legislative consultant, J. T. Rutherford.

Sincerely,

Gerald D. Dodd, M.D.

Gerald D. Dodd, M.D.
Chairman, Board of Chancellors

Senator **Quayle**. That concludes our hearings today and the committee will stand adjourned.

[Whereupon, at 12:05 p.m., the committee recessed, to reconvene subject to the call of the Chair.]

○